FALL 1998

TRIALS SEARCH GUIDE

HIV Clinical Trials in California

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1998

Compiled by the Community Consortium
UCSF AIDS Program at San Francisco General Hospital

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HIV Clinical Trials in California

Compiled by the Community Consortium
UCSF AIDS Program at San Francisco General Hospital

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About the Community Consortium

The purpose of the Community Consortium is to improve the quality of primary medical care for people living with HIV/AIDS in the San Francisco Bay Area.

The Community Consortium is an association of licensed health care providers who care for the majority of people with HIV infection in the Bay Area. We work in private practices, neighborhood clinics, community hospitals, jails and correctional systems, academic medical centers and health maintenance organizations. Our administrative base is the UCSF AIDS Program at San Francisco General Hospital.

We achieve our purpose by ensuring that primary care providers in the Bay Area have the latest information on the most effective treatments for HIV disease, by evaluating a broad range of promising treatments and treatment strategies, and by influencing public policy that directly impacts the provision of primary medical care to people with HIV infection. We believe that all people with HIV infection should have access to the highest quality health care, and that this goal can only be achieved if there is cooperation among health care providers and people with HIV infection, and if existing resources are maximized through innovative and collaborative approaches to improving health care.

Our vision is that all people with HIV infection in our community will benefit from advances in HIV care, and that we will see the day when HIV is no longer a life-threatening disease.

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Introduction

RM

The *Trials Search Guide to HIV Clinical Trials in California* is a listing of all the clinical trials currently open in California that are related to HIV and AIDS. The *Guide* is primarily a resource for people infected with HIV, but is also used by HIV providers to educate their HIV-infected clients and patients.

A clinical trial is a study that tests experimental medicines in human beings. Any drug that is approved by the Food and Drug Administration (FDA) must undergo several clinical trials first. For people with HIV, clinical trials provide an opportunity to receive promising new medical treatments, usually for free.

Because the drugs tested are experimental, clinical trials involve some risks for patients. The *Guide* only includes studies that have been reviewed and approved by an Institutional Review Board, which is a committee set up to ensure that studies involving human subjects are ethical and scientifically sound. No endorsement is made of any trial described in the *Guide*, but every reasonable effort has been made to present information that is accurate, comprehensive and up-to-date. However, eligibility and other criteria are subject to change, trials may close to patient enrollment at any time, and new trials may begin without our knowledge.

Included in this *Guide* is a questionnaire form you can use to receive a personalized *Trials Search* listing of all the clinical trials for which you may be eligible to join within your area of California. This free service is based on confidential information about your medical history and current health status that you supply us on the questionnaire form. Call (800) 492-5777 if you would like to receive a second *Trials Search* questionnaire form, or if you have any questions about the service.

In addition, the Community Consortium welcomes information about all clinical trials available throughout the United States for inclusion in the national *Trials Search* database. Any trial that has been reviewed by an Institutional Review Board may be included. If you have information that may be appropriate for publication, please call the Consortium at (415) 476-5777 or (800) 492-5777.

Trials Search and the database HIV Clinical Trials in the United States are also available on the Internet at:

http://hivinsite.ucsf.edu/tsearch

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• Research staff at more than 60 trial sites who furnished the bulk of the information contained in the Guide. This project would not have been possible without their considerable expertise and generous contribution of time and energy.

The following publications for their reliability and usefulness:

• *AIDS/HIV Treatment Directory* published by the American Foundation for AIDS Research (AmFAR).
• *Bulletin of Experimental Treatments for AIDS (BETA),* from the San Francisco AIDS Foundation.
• *Treatment Issues* from the Gay Men's Health Crisis (GMHC) for the Glossary of Medical Terms which is a reference and basis for some of our glossary entries. The online Guide uses the GMHC Glossary as a whole.

An Association of Bay Area
HIV Health Care Providers

The Community Consortium is part of the
UCSF AIDS Program at San Francisco General Hospital.

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How to use this Guide

The *Trials Search Guide* is written for people who are living with HIV disease and their health care providers. The *Guide* should be used in combination with other resources for learning about HIV disease. People interested in participating in clinical trials should discuss them with their physicians or health care providers. The *Guide* is most useful to people who already know something about their own health and about HIV. If you think you need to learn more, talk to your health care provider and contact some of the Resources beginning on page 117.

Understandable language

When learning about HIV and clinical trials, one of the stumbling blocks can be confusing medical jargon. We have tried to avoid using technical language whenever possible, but sometimes there is no simple way to describe technical information. If you come across a word or idea that you don't understand, you can check the Glossary on page 123. It may be helpful to discuss any remaining questions with your health care provider, or the contact person listed for the clinical trial. More information is also available from one or more of the Resources listed on page 117.

Other programs for treatment access

Receiving treatment for HIV and its related conditions can be complicated and confusing. If a medication you are seeking is not being studied in a clinical trial in your area, check page 85 for a listing of Expanded Access, Compassionate Use and Treatment IND Programs. If the treatment has been approved for sale, but you need help to pay for it, check the list of AIDS Drug Assistance Covered Drugs and pharmaceutical company sponsored Patient Assistance programs on pages 89 - 96.

Questions about clinical trials, and issues for special groups

The *Guide* also includes sections that answer common questions about clinical trials, describe how to join a clinical trial, and discuss issues about clinical trials for women, children, youth and people who use injection drugs. These sections are found on pages 97 through 109.

Trial Finder and Trial Descriptions

The 150 trials listed in the *Guide* are arranged by the disease or condition being studied, or by the group of people for whom the study is intended. Trial Finder on pages 3 - 8 is a quick reference for trials in which you may be interested.

If you are interested in a certain drug or treatment for a particular disease, you can also look it up in the Index, starting on page 131. The Index will tell you which page to turn to in the *Guide*.

How to use this Guide

For each clinical trial, we include the following information:

Title: This is the official name of the trial. Most trials also have letters or numbers given before the title. This is the protocol number. For example, ACTG 276 means this is AIDS Clinical Trials Group study number 276.

Type of Treatment: This lists the type or "class" of drugs being tested in the study. The different types of anti-HIV drugs attack the virus in different ways. Older anti-HIV drugs such as AZT (also called 2DV), ddI, ddC and d4T are all a type of drug called a "nucleoside analog". Some newer drugs are called "protease inhibitors" and "non-nucleoside reverse transcriptase inhibitors".

Purpose: This is what the researchers are trying to learn from the trial. Below are a few of the most common reasons why studies are done.

- To learn if a drug is safe for people to take.
- To learn if a drug works.
- To compare two or more drugs.
- To compare two or more doses of the same drug.

About the study: This section describes what will happen during a trial, from the patient's perspective. We tell you how long the trial lasts, if you will know what drugs you are taking, how the drug is given (for example, pill, liquid or injection), if there are an unusual number of required visits to the clinic, or if you need to stay in the hospital.

Required: These are the entry requirements that you must meet before you can join the study. These are sometimes called "inclusion criteria." We have space to list only a few of the most important entry requirements. In many cases, there will be others.

Not allowed: You cannot join the study if you fit any of these criteria. These are sometimes called "exclusion criteria." Again, only the most important exclusion criteria are included. You may not be able to join this particular study because there is a good chance that you would be harmed by the study drug. Researchers examine your medical history and your laboratory tests to make sure you are not at "high risk" for experiencing harmful side effects. Many clinical trials require that your laboratory tests be "within normal limits," or at least in a safe range. This is to make sure you don't already have a medical problem that might become worse if you take the drug.

Women who are pregnant or breastfeeding may also not be able to join a clinical trial. This is because it is not known if taking the drug will harm the baby. Usually, women who have sex with men, and men who have sex with women, must agree to use birth control while they are in the study.

Location: This is where you need to go to participate in the study (the study "site"). We also give you the name of the person to call if you are interested. In most cases, you don't have to be a patient at the hospital or clinic where the study is located in order to join the study. For some studies, your doctor must contact the site first.

Trial Finder

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New

I. HIV Infection: Amprenavir, Abacavir, Efavirenz, Adefovir dipivoxil

Title:

ACTG 398: A Phase II, Randomized Trial of Amprenavir as Part of Dual Protease Inhibitor Regimens (Placebo Controlled) in Combination With Abacavir, Efavirenz and Adefovir Dipivoxil Versus Amprenavir Alone in HIV Infected Subjects With Prior Exposure to Approved Protease Inhibitors and Loss of Virologic Suppression as Reflected by a Plasma HIV-1 RNA Concentration of 1,000 Copies/mL or More

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
Fortovase™: antiretroviral, protease inhibitor
DMP 266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
Indinavir: antiretroviral, protease inhibitor
Adefovir dipivoxil: antiretroviral, reverse transcriptase inhibitor, nucleotide analog
1592U89: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Invirase™: antiretroviral, protease inhibitor
141W94: antiretroviral, protease inhibitor

Purpose:

This study will use saquinavir, nelfinavir and indinavir in combination with amprenavir (141W94), abacavir (1592U89), efavirenz (DMP 266) and adefovir dipivoxil. The purpose of the study is to see if these drugs are safe when combined and to see if they can produce a decrease in the amount of HIV in the blood to an undetectable level.

About the study:

All patients will take amprenavir (an investigational protease inhibitor), abacavir, efavirenz and adefovir dipivoxil. In addition, patients are assigned by chance to receive saquinavir (Fortovase™), indinavir, nelfinavir or a placebo. Patients will not know if they are taking a placebo or a second protease inhibitor. All medications are pills and taken by mouth. Study visits are every two weeks for the first month, then once a month until the end of the study. Patients will take study medications for at least 48 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 1,000 copies/mL for two consecutive tests while on at least 16 weeks of Fortovase™, indinavir, nelfinavir, ritonavir, or Invirase™ therapy
- HIV positive
- At least 13 years old
- Prior exposure to one, two or three protease inhibitors. Exposure is defined as more than seven days use of protease inhibitors

Not allowed:

- Treatment for an acute illness within 14 days of study entry
- Unexplained fever of more than 38.5 C or 101.3 F for any seven days or chronic diarrhea, defined as more than three liquid stools per day persisting for 15 days, within 30 days of study entry
- Any cancers requiring chemotherapy
- Use of erythropoietin, G-CSF or GM-CSF within 30 days prior to study entry
- Use of interferons, interleukins, HIV vaccines, or any active immunizations within 30 days of study entry
- Any chemotherapy or radiation therapy within 30 days of study entry
- Prior exposure (defined as more than seven days use) to amprenavir, abacavir, efavirenz or adefovir dipivoxil
- Exposure to more than three protease inhibitors
- Women who are pregnant or breastfeeding
- Severe peripheral neuropathy within 60 days of study entry
- Hepatitis within 90 days of study entry

Location:

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

Stanford University Medical Center
Sandra Valle, PA-C
(650) 723-8169

UCSF AIDS Clinic
David Gary, RN
(415) 476-9296, ext. 354

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

New

2. HIV Infection: Amprenavir, Efavirenz, Fortovase™, Indinavir, Ritonavir, AZT, 3TC, d4T, ddI

Title:

ACTG 400: A Phase II, Randomized, Open-Label Comparative Trial of Salvage Antiretroviral Therapies for HIV-Infected Individuals With Virological Evidence of Nelfinavir Treatment Failure as Reflected by Plasma HIV RNA Concentration of 1,000 Copies/mL or More

Type of treatment:

141W94: antiretroviral, protease inhibitor
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Ritonavir: antiretroviral, protease inhibitor
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Fortovase™: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
DMP 266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)

Purpose:

To compare four different drug combinations for safety and to see how many patients will have an undetectable amount of HIV in the blood (less than 200 copies/mL) after 8 and 24 weeks of treatment and to see how long they remain undetectable over time.

About the study:

Patients are assigned by chance to be in one of four groups. **Group A** will take ritonavir, Fortovase™, efavirenz and two NRTIs; **Group B** will take indinavir, efavirenz and two NRTIs; **Group C** will take amprenavir, efavirenz and two NRTIs; and **Group D** will take indinavir, amprenavir, efavirenz and two NRTIs. The NRTI pairs used in this study are AZT + 3TC; d4T + 3TC; d4T + ddI; or AZT + ddI. Patients will know which medications they are taking and will take these study drugs for 48 weeks. Study visits are every two weeks for the first month, then once a month for four months, then every two months for the remainder of the study. Viral load tests will be done regularly and, if after eight weeks of treatment, the viral load shows that the study treatments are not working effectively, a blood test will be done (genotype and phenotype test) to see if the HIV virus is resistant to any of the study drugs. If the study drugs are clearly not working, patients will have a choice of continuing with study drugs or discontinuing the study. The study lasts about one and a half years.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 1,000 copies/mL on two consecutive occasions following current use and at least 16 weeks of uninterrupted nelfinavir therapy
- HIV positive
- At least 13 years old

Not allowed:

- Acute treatment for an infection or other medical illness within 14 days of study entry
- More than seven days use of amprenavir (141W94), Fortovase™ (saquinavir), indinavir or ritonavir
- Prior use of any NNRTIs (nevirapine, delavirdine, efavirenz)
- Unexplained fever of more than 38.5 C or 101.3 F for any seven days within 30 days of study entry
- Chronic diarrhea (not related to nelfinavir use) defined as more than three liquid stools per day persisting for 15 days, within 30 days of study entry
- Any cancers requiring systemic chemotherapy
- Use of EPO, G-CSF, GM-CSF, interferons, interleukins, HIV vaccines, active immunizations or investigational drugs within 30 days of study entry
- Women who are pregnant or breastfeeding
- Moderate to severe peripheral neuropathy within 60 days of study entry
- Chemotherapy or radiation theapy within 30 days of study entry
- Hepatitis within 90 days of study entry

Location:

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

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UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

KNOW YOUR OPTIONS!

TRIALS SEARCH

CONFIDENTIAL

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FAST!

Over 150 clinical trials are available to people with HIV disease.

What is Trials Search?

If you have HIV, **Trials Search** can provide you with a personalized, up-to-date list of HIV clinical trials in the United States. Clinical trials are often the first place you can gain access to promising new medical treatments. They are an important option for anyone with HIV.

Trials Search uses the confidential medical information you provide to us, and the study criteria given to us by researchers, to produce your personalized list of clinical trials.

Each study listing includes:

- Name of study
- Purpose of study
- What the study involves
- Who can join the study
- Whether the study pays participants
- Names and phone numbers of people to call if you want to join the study or ask questions.

How to receive your own Trials Search Report

On the reverse side of this page is a brief questionnaire that asks for information about your current health and your medical history. This information is matched with all of the clinical trials in our computer database. Within two working days of receiving your completed questionnaire we will send you a **Trials Search** report.

It is important to answer each of the questions completely. If you have problems filling out the questionnaire, call our toll-free number for assistance. Your doctor or other health care provider can also help. A nurse or medical office staff person may be able to answer these questions on the telephone.

Trials Search *is a service provided by the Community Consortium, an association of Bay Area HIV health care providers. The Community Consortium is a part of the UCSF AIDS Program at San Francisco General Hospital.*

Contact Information:

All information is mailed to you in a plain envelope. In some cases we may need to call you to clarify information on your questionnaire. Your name and other personal information is held in the strictest confidence.

NAME _____

ADDRESS _____

CITY _____ STATE _____ ZIP _____

TELEPHONE _____ FAX (for response by Fax) _____

May we leave a message? ❒ yes ❒ no Is this a private Fax? ❒ yes ❒ no

May we contact you by mail in the future? ❒ yes ❒ no

How did you hear about **Trials Search**? ❒ Doctor's Office/Clinic ❒ Friend ❒ Ad ❒ Community Agency ❒ Other _____

For your report complete BOTH SIDES and return by fax or mail to:

Trials Search/Community Consortium

3180 18th Street, #201, San Francisco, CA 94110

Toll-free: **1-(800) 492-5777** Phone: **(415) 476-5777** Fax: **(415) 502-8686**

E-mail: **tsearch@sfaids.ucsf.edu** Internet: **http://hivinsite.ucsf.edu/tsearch**

TS11098

Trials Search Questionnaire

Date Completed: ___/___/___ (mo/day/year) Date of Birth: ___/___/___ (mo/day/year)

Sex: ❒ Male ❒ Female First initial & last initial: _____ _____

Medical History:

Absolute CD4 Cell Count (T-helper cells):_____ HIV RNA Viral Load: _____

Check the first column **(Past)** for each condition **you have had in the past,** but no longer have.
Check the second column **(Current)** for each medical condition that **you currently have.**

Past	Current	
○	❒	Anal or Genital Warts
○	❒	Candidiasis - Esophageal (throat)
○	❒	Candidiasis - Oral (thrush)
○	❒	Candidiasis - Vaginal (recurrent yeast infection)
○	❒	Cryptococcal Meningitis
○	❒	Cryptosporidiosis
○	❒	CMV (Cytomegalovirus) - Retinitis
○	❒	CMV - Gastrointestinal
○	❒	Dementia
○	❒	Diarrhea - HIV Related
○	❒	Hairy Leukoplakia
○	❒	Herpes Simplex Virus
○	❒	Herpes Zoster Virus (shingles)
○	❒	ITP (Immune Thrombocytopenia Purpura)
○	❒	KS (Kaposi's sarcoma) - skin and mouth
○	❒	KS (Kaposi's sarcoma) - internal organs

Past	Current	
○	❒	Lymphoma - Hodgkin's
○	❒	Lymphoma - Non-Hodgkin's
○	❒	MAC or MAI (Mycobacterium avium Complex)
○	❒	Molluscum Contagiosum
○	❒	Pancreatitis
○	❒	PCP (Pneumocystis carinii Pneumonia)
○	❒	Peripheral Neuropathy
○	❒	PID (Pelvic Inflammatory Disease)
○	❒	PML (Progressive multifocal leukoencephalopathy)
○	❒	Sinusitis
○	❒	Syphilis
○	❒	Toxoplasmosis
○	❒	Tuberculosis (TB)
○	❒	Wasting Syndrome (unintended weight loss > 10%)
○	❒	Other:

HIV Medication History:

Check the first column **(Past)** for each medication **you have taken in the past,** but no longer take.
Check the second column **(Current)** for each medication that **you currently take.**

Past	Current	
○	❒	141W94 (amprenavir)
○	❒	1592U89 (abacavir)
○	❒	3TC (Epivir)
○	❒	Acyclovir (Zovirax)
○	❒	Adefovir dipivoxil (bis-POM PMEA, Preveon))
○	❒	Alpha-Interferon (Wellferon, Roferon-A, Intron-A)
○	❒	Amikacin (Amikin)
○	❒	Amphotericin-B (Fungizone, Ablacet)
○	❒	Atovaquone (Mepron)
○	❒	Azithromycin (Zithromax)
○	❒	AZT (Retrovir, Zidovudine)
○	❒	Bactrim/Septra (TMP-SMX)
○	❒	Chemotherapy - local
○	❒	Chemotherapy - systemic
○	❒	Cidofovir (Vistide)
○	❒	Clarithromycin (Biaxin)
○	❒	Clindamycin (Cleocin)
○	❒	Clofazimine (Lamprene)
○	❒	Combivir (AZT/3TC Fixed Dose)
○	❒	d4T (Satvudine)

Past	Current	
○	❒	Dapsone
○	❒	ddC (Zalcitabine, HIVID)
○	❒	ddI (Didanosine, Videx)
○	❒	Delavirdine (Rescriptor, U-90)
○	❒	DMP 266 (Sustiva, efavirenz)
○	❒	DNCB
○	❒	EPO (Epogen, Procrit)
○	❒	Ethambutol (Myambutol)
○	❒	Fluconazole (Diflucan)
○	❒	Fortovase (saquinavir SGC)
○	❒	Foscarnet (Foscavir)
○	❒	Ganciclovir - IV (Cytovene)
○	❒	Ganciclovir - oral
○	❒	Ganciclovir - implants
○	❒	G-CSF (Neupogen, Filgastrim)
○	❒	Hydroxyurea (Hydrea)
○	❒	Indinavir (Crixivan)
○	❒	INH (Isoniazid)
○	❒	Interleukins (2, 4, 10, 12)
○	❒	Invirase (Saquinavir)
○	❒	Itraconazole (Sporanox)
○	❒	Ketoconazole (Nizoral)
○	❒	Marinol (Dronabinol)

Past	Current	
○	❒	Megace (Megesterol acetate)
○	❒	Mycelex (Clotrimazole)
○	❒	NAC (Mucomyst)
○	❒	Nelfinavir (Viracept)
○	❒	Nevirapine (Viramune)
○	❒	Nystatin (Mycostatin)
○	❒	Aero Pentamidine (Nebupent)
○	❒	IV Pentamidine
○	❒	Pyrimethamine (Daraprim)
○	❒	Remune (HIV Immunogen)
○	❒	Rifabutin (Mycobutin)
○	❒	Rifampin (Rifadin, Rimactane)
○	❒	Ritonavir (Norvir)
○	❒	Serostim (growth hormone)
○	❒	Sparfloxacin
○	❒	Testosterone
○	❒	Thalidomide
○	❒	HIV Vaccine
○	❒	Other Antifungal
○	❒	Other Antiretroviral
○	❒	Other Immune Modulator
○	❒	Other:

Have Questions? Need Help? Call (415) 476-5777 (local) or 1-800-492-5777 (toll free).

New

3. HIV Infection: Delavirdine, MKC-442, ddI, d4T, Hydroxyurea

Title:

ICC 603: A Phase II, 24-Week, Open-Label Study Designed to Evaluate the Pharmacokinetics, Safety, Tolerability and Efficacy of Novel Combination Therapy with Videx (Didanosine), Zerit® (Stavudine), Rescriptor® (Delavirdine Mesylate) and MKC-442 (with or without Hydroxyurea) for the Treatment of HIV-1 Infected Patients Who Failed Previous Protease Inhibitor Treatment

Type of treatment:

ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Hydroxyurea: cellular inhibitor
Delavirdine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
MKC-442: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if this four-drug combination is safe, well-tolerated and effective in lowering the amount of HIV in the blood of HIV-positive patients who have failed (viral load > 5,000 copies) protease inhibitor treatment. To see how these drugs are processed by the body.

About the study:

All patients will take ddI, d4T, delavirdine and MKC-442. There are no placebos in this study. All medications are taken by mouth. Patients who show virologic failure (do not achieve an adequate decrease in HIV viral load) may add hydroxyurea to their treatment or discontinue from the study. After 24 weeks, patients who have shown a virologic response will be eligible to continue treatments until the patient shows virologic failure. Study visits are every two weeks for the first month, then once a month until six months. Patients continuing beyond 24 weeks will have study visits every three months. The study lasts at least six months.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: between 5,000 and 50,000 copies/mL after six months of continuous protease inhibitor treatment
- HIV positive
- At least 18 years old

Not allowed:

- Prior use of any NNRTIs, such as delavirdine, nevirapine or Sustiva® (efavirenz)
- Prior use of MKC-442, ddI or d4T
- Women who are pregnant or breastfeeding

Location:

Pacific Oaks Research Group
Donna Morales, RN
(310) 360-8800

New

4. HIV Infection: Efavirenz, Adefovir dipivoxil, Hydroxyurea, ddI

Title:

AdD Study: Clinical, Virological and Immunological Utility of Combination Efavirenz (DMP 266), Adefovir Dipivoxil, ddI and Hydroxyurea in Drug Experienced HIV Infected Patients

Type of treatment:

ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Adefovir dipivoxil: antiretroviral, reverse transcriptase inhibitor, nucleotide analog
DMP 266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
Hydroxyurea: cellular inhibitor

Purpose:

To see if efavirenz (also called DMP 266 or Sustiva®) and adefovir dipivoxil (also called Preveon), ddI and hydroxyurea are safe and effective in lowering the amount of HIV in the blood. Patients will have drug resistance testing (genotype testing) to see if they are resistant to currently licensed antiretroviral medications.

About the study:

Patients whose resistance profile (genotype test) categorizes them as highly drug-experienced will take efavirenz, adefovir dipivoxil, ddI and hydroxyurea. All medications are taken by mouth. Study visits are every two weeks for the first month, then once a month. The study lasts six months with an option for an additional six-month extension.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: more than 10,000 copies/mL
- HIV positive
- At least six months of treatment with at least one protease inhibitor and two NRTIs (AZT, ddI, ddC, 3TC, d4T)
- Evidence of some resistance to both protease inhibitors and NRTIs (genotype testing done by research staff)

Not allowed:

- Prior use of efavirenz or adefovir dipivoxil
- More than three days use of any NNRTI, such as nevirapine or delavirdine
- NNRTI-specific resistance

Location:

Stanford University Medical Center
Jane Norris, PA-C
(650) 723-2805

New

5. HIV Infection: Efavirenz, Indinavir, Nelfinavir

Title:

ICC 602: A Phase II, 48-Week, Open-Label Study Designed to Evaluate the Safety, Tolerability and Efficacy of a Simplified Dosing Regimen of Viracept (Nelfinavir Mesylate) 1250 mg q12h, (Indinavir Sulfate) 1200 mg q12h, and Sustiva® (Efavirenz, DMP 266) 600 mg q24h for the Treatment of HIV-1 Infection in Non-Nucleoside Reverse Transcriptase Inhibitor and Protease Inhibitor Naive Patients

Type of treatment:

Indinavir: antiretroviral, protease inhibitor
Nelfinavir: antiretroviral, protease inhibitor
DMP 266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)

Purpose:

To see if this three-drug combination is safe, well-tolerated and effective in lowering the amout of HIV in the blood of patients who have never taken protease inhibitors or NNRTIs, such as delavirdine, nevirapine or Sustiva®. To see how these three drugs are processed by the body.

About the study:

All patients will take nelfinavir (Viracept), indinavir (Crixivan®) and Sustiva® (DMP 266, efavirenz). There are no placebos in this study. After 12 weeks, patients showing a virologic response (a drop in the HIV RNA viral load level) will continue for an additional 36 weeks. Patients who show virologic failure at Week 12 wil be discontinued from the study. Study visits are every two weeks for the first month, then once a month until the end of the study. The study lasts about one year.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 10,000 copies/mL
- HIV positive
- At least 13 years old

Not allowed:

- Prior use of any protease inhibitors or NNRTIs, such as delavirdine, nevirapine or efavirenz (DMP 266, Sustiva®)
- Women who are pregnant or breastfeeding

Location:

Pacific Oaks Research Group
Donna Morales, RN
(310) 360-8800

New

6. HIV Infection: Efavirenz, Nelfinavir, Combivir™, ddI, d4T, Indinavir, Amprenavir, Hydroxyurea

Title:

ACTG 384: Study of Protease Inhibitor And/Or Non-Nucleoside Reverse Transcriptase Inhibitor With Dual Nucleosides in Initial Therapy of HIV Infection

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
DMP 266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
141W94: antiretroviral, protease inhibitor
Hydroxyurea: cellular inhibitor
Combivir™: antiretroviral, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see how well different combinations of drugs can decrease the amount of HIV in the blood (viral load) to less than 200 copies/mL. To see how well each combination keeps the virus at such a low level. To see whether it is better in the long run to have received three or four drugs in your first treatment combination.

About the study:

Patients are assigned by chance to receive ddI + d4T **or** to receive 3TC + AZT. Patients are also assigned by chance to receive efavirenz (Sustiva®, DMP 266) **or** nelfinavir (Viracept) **or** both. This study is partially blinded,

which means that patients will not know if they are receiving efavirenz, nelfinavir, or both until the study ends. All medications are pills and taken by mouth. During the study, patients will be switched to a new treatment group if the study treatments they are taking are not working. Treatment failure will be determined by HIV RNA viral load blood tests. Study visits are once a month for the first six months, then once every two months until the end of the study. The study lasts about three years.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 500 copies/mL
- HIV positive
- At least 13 years old

Not allowed:

- Seven or more days use of any antiretroviral medications
- Any vaccination within 14 days of study entry
- Use of any immunomodulators (such as interleukins or interferons) or investigational drugs within 30 days of study entry
- Acute treatment for an infection or other medical illness within 14 days of study entry
- Unexplained fever of 38.5 C or 101.3 F for any seven days, within 30 days of study entry
- Chronic diarrhea, defined as more than three liquid stools per day persisting for 15 days, within 30 days of study entry
- Any AIDS-related cancers other than minimal (five or less lesions) KS of the skin, requiring chemotherapy
- Hepatitis within 30 days of study entry
- Use of erythropoietin, G-CSF or GM-CSF within 30 days of study entry
- Past or current severe peripheral neuropathy
- Pancreatitis within three years of study entry
- Active alcohol and/or substance abuse
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center ACTU
Connie Olson, RN
(323) 343-8279

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

Stanford University Medical Center
Jane Norris, PA-C
(650) 723-2805

UCSF AIDS Clinic
David Gary, RN
(415) 476-9296, ext. 354

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

New

7. HIV Infection: F-ddA, d4T, Indinavir

Title:

FddA-B001: A Phase II Randomized, Parallel Group, Multiple Dose Study of Lodenosine (FddA) in Combination with Stavudine and Indinavir in Antiretroviral-Naive Adult Patients

Type of treatment:

d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
F-ddA: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor

Purpose:

To see if three different doses of lodenosine (FddA) are safe, well-tolerated and effective when combined with d4T and indinavir, in lowering the amount of HIV in the blood of HIV-infected patients who have no antiretroviral experience.

About the study:

Patients are assigned by chance to receive one of three doses of FddA to take with d4T and indinavir **or** to take 3TC with d4T and indinavir. Patients will know which medications and doses they are taking. All medications are pills and taken by mouth. After screening, study visits are at Months 3, 6, and 12. The study lasts about one year.

Required:

- CD4 cell (T-cell) range: at least 200
- Viral load range: at least 5,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- More than seven days use of any NRTIs, such as AZT, ddI, ddC, 3TC or d4T
- Prior use of any protease inhibitors or NNRTIs, such as delavirdine, nevirapine or efavirenz
- Current opportunistic infections
- Women who are pregnant or breastfeeding
- Use of any investigational drug within three months of study entry
- Current severe peripheral neuropathy
- Any cancers which required chemotherapy or radiation therapy within the past three years, excluding basal or squamous cell carcinoma of the skin, cervical cancer, or KS of the skin

- Use of immunomodulators, such as interferons or interleukins within four weeks of study entry
- Use of any HIV vaccine within three months of study entry

Location:

Center for Special Immunology - Irvine
Sandra Casserella, RN
(949) 753-0670

New

8. HIV Infection: FTC

Title:

FTC-303: A Randomized, Open-Label Study of FTC versus Lamivudine in Patients on a Stable Triple Antiretroviral Therapy Regimen Containing Lamivudine and a Protease Inhibitor

Type of treatment:

FTC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
FTC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To observe the viral resistance of both FTC and 3TC .

About the study:

Patients are assigned by chance to switch from 3TC to FTC or to remain on 3TC as part of their antiretroviral combination therapy. Patients will know which medications they are taking. Study visits are every two weeks for the first month, then once a month until the end of the study. The study lasts 48 weeks. Patients will be paid for their participation.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: undetectable (< 400 copies/mL)
- HIV positive
- At least 18 years old
- Combination therapy consisting of an NRTI (such as AZT, ddC, ddI, d4T, 3TC) and a protease inhibitor for at least eight weeks prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Severe chronic diarrhea
- Active alcohol and/or substance abuse
- Current opportunistic infections
- Prior use of any NNRTIs, such as nevirapine, delavirdine or DMP 266 (efavirenz, Sustiva®)

Location:

East Bay AIDS Center
Jeremy Swartzberg
Weena Joshi
(510) 204-2782

Kaiser San Francisco - HIV Research Unit
Anna Dowling, RN
(415) 202-3487 **OR**
Brian Goodroad, RN, MS
(415) 202-3480

LAC-USC Medical Center ACTU
Connie Olson, RN
(323) 343-8279

UCSF AIDS Program at SFGH/ICTG
Anna Smith, RN
(415) 476-9296, ext. 313

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

ViRx, Inc. - Palm Springs
Tom Clover, RN
(760) 864-6266

New

9. HIV Infection: Indinavir, Nelfinavir, d4T, 3TC

Title:

Merck 079-00: A Multi-Center, Double Blind, 24-Week Study to Compare the Safety and Activity of Indinavir Sulfate/ d4T/3TC Versus Indinavir Sulfate/ Nelfinavir Meslayte/d4T/3TC in HIV-Infected Individuals

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To compare the antiviral activity, safety and tolerance of indinavir, d4T and 3TC with and without nelfinavir.

About the study:

All patients will take indinavir (Crixivan®), d4T and 3TC. In addition, patients are assigned by chance to take nelfinavir (Viracept) or placebo. Neither patients nor their doctors will know which they are taking until the study ends. All medications are pills and taken by mouth. After two screening visits and one baseline visit, study visits will be once a month until the study ends. Patients will take study medications for 24 weeks.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: at least 10,000 copies/mL
- HIV positive
- At least 18 years old
- Rifabutin or rifampin must be discontinued 30 days prior to study entry

Not allowed:

- Prior use of indinavir or nelfinavir
- Prior use of 3TC for more than 14 days (two weeks)
- Prior use of any other protease inhibitor for more than 42 days (six weeks)
- Women who are pregnant or breastfeeding
- Use of any investigational drugs, immunomodulators (such as interleukins, interferons) or GM-CSF, G-CSF or erythropoietin within 30 days of study entry
- Active alcohol and/or substance abuse
- Acute opportunistic infections or cancers
- Unexplained, chronic diarrhea, defined as three or more loose stools per day persisting for 14 days or more, within eight days of study entry
- KS of the internal organs
- Acute hepatitis due to any cause

Location:

AIDS Community Research Consortium
Sharon O'Leary, RN
(650) 364-6563

AIDS Healthcare Foundation
Deewee McDermott, RN
(213) 913-3953

HIVCare, Saint Francis Memorial Hospital
Mark Bowers
(415) 353-6215

Kaiser Permanente - Los Angeles
Rosa Kawahira, RN
(213) 783-8172

Kaiser San Francisco - HIV Research Unit
Barbara LeMaire, RN, MS
(415) 202-3486

New

10. HIV Infection: Interleukin-2

Title:

CPCRA 059: A Randomized, Open-Label Study of the Impact of Two Doses of Subcutaneous Recombinant IL-2 (Proleukin) on Viral Burden and CD4+ Cell Count in Patients With HIV-1 Infection and CD4+ Cell Counts of 350/mm^3 or More

Type of treatment:

Interleukin-2: immune modulator

Purpose:

To compare the effects of two doses of inlerleukin-2 (also called Proleukin) and no interleukin-2 on HIV viral load and CD4 cell (T-cell) counts

About the study:

Patients are assigned by chance to receive one of two doses of interleukin-2 or to receive no interleukin-2. Patients will know which dose of interleukin-2 they are receiving, if any. Interleukin-2 is given by injection under the skin for five consecutive days every eight weeks for at least three cycles. A cycle is defined as 8 calendar weeks, including the five-day consecutive period of injections. After three cycles, additional cycles may be given depending on the patient's CD4 cell count. Interleukin-2 can not be given more frequently than every six weeks. Study visits are once a month for the first year, then every four months thereafter. The overall study lasts for one year after the last patient has been enrolled. Patients enrolled in this study may be encouraged to participate in an international Phase III study if and when it is implemented.

Required:

- CD4 cell (T-cell) range: at least 350
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Must be on or starting antiretroviral therapy at the time of enrollment and must take antiretroviral drugs when taking interleukin-2

Not allowed:

- Women who are pregnant or breastfeeding
- Prior use of interleukin-2
- Any cancers requiring chemotherapy
- Use of any steroids, immunomodulators (such as interferons or other interleukins), chemotherapy or hydroxyurea within four weeks of study entry
- Seizure disorder

Location:

Community Consortium
Available at the locations listed on page 115
(415) 476-9554

New

11. HIV Infection: PMPA

Title:

GS-98-902: A Phase II, Randomized, Double-Blind, Placebo Controlled Study of the Safety and Antiviral Activity of the Addition of PMPA Prodrug to Combination Antiretroviral Regimens in Treatment Experienced HIV-Infected Patients

Type of treatment:

PMPA: antiretroviral, nucleoside analog

Purpose:

To see if PMPA is safe and effective for treating HIV infection when combined with other anti-HIV drugs.

About the study:

Patients are assigned by chance to receive one of three doses of PMPA or placebo. Neither patients nor their doctors will know which they are taking until the study ends. PMPA and its placebo are pills and patients will take four pills a day after a meal. Study visits are every week for the first two weeks, then once a month for the remainder of the study. Patients may change any of their anti-HIV medications after four weeks of taking PMPA. After 24 weeks, patients who are taking placebo will be offered open-label (real) PMPA. The study lasts about one year and patients who are able to complete 48 weeks of treatment without bad side effects may be able to continue taking PMPA.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: between 400 and 50,000 copies/mL
- HIV positive
- Between 18 and 65 years old
- Stable (no changes) antiretroviral therapy consisting of no more than three drugs for at least eight weeks prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Inability to take oral medications due to chronic diarrhea and/or nausea/vomiting
- Active, serious infections (other then HIV) which require IV antibiotics within 15 days of study entry
- Any cancers, other than KS of the skin or basal cell carcinoma of the skin. Patients must not have had any chemotherapy within 30 days of study entry or the need for such throughout the study
- Active alcohol and/or substance abuse

Location:

East Bay AIDS Center
Jeremy Swartzberg
Weena Joshi
(510) 204-2782

Harbor-UCLA Medical Center
Dena Duran, LVN
(310) 222-3848

San Francisco VA Medical Center
Sandy Charles, RN
(415) 221-4810, ext. 3763

New

12. HIV Infection: Preveon®, Abacavir, Sustiva®, Amprenavir

Title:

ICC 605: A Phase II, 24-Week, Open-Label Study Designed to Evaluate the Safety, Tolerability and Efficacy of Novel Quadruple Combination Therapy with Preveon® (Adefovir Dipivoxil; bis-POM PMEA), Abacavir (1592U89), Sustiva® (Efavirenz; DMP 266) and Amprenavir (141W94) for the Treatment of HIV-1 Infection in Patients Who Have Failed Previous Protease Inhibitor Treatment

Type of treatment:

1592U89: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
DMP 266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
Adefovir dipivoxil: antiretroviral, reverse transcriptase inhibitor, nucleotide analog
141W94: antiretroviral, protease inhibitor

Purpose:

To see if this four-drug combination is safe, well-tolerated and if it has any effect on the amount of HIV in the blood of patients who have failed previous protease inhibitor treatment.

About the study:

All patients will take Preveon® (adefovir dipivoxil), abacavir (1592U89), efavirenz (DMP 266, Sustiva®) and amprenavir (141W94). There are no placebos in this study. All medications are taken by mouth. Patients will take these medications for 24 weeks. Study visits are every two weeks for the first month, then once a month until Week 24. Patients who have shown a response to these medications at Week 24 may continue to take these medications until they are FDA-approved and commercially available in the United States. Study visits for those continuing after Week 24 will be every 12 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 2,000 copies/mL **after** six months of continuous protease inhibitor treatments other than 141W94 (amprenavir)
- HIV positive
- At least 13 years old

Not allowed:

- Prior use of adefovir dipivoxil, abacavir, DMP 266 or amprenavir
- Prior use of any other NNRTIs, such as delavirdine or nevirapine
- Women who are pregnant or breastfeeding

Location:

Pacific Oaks Research Group
Donna Morales, RN
(310) 360-8800

New

13. HIV Infection: Preveon®, ddI, Sustiva®, 3TC

Title:

ICC 604: A Phase II, 48-Week, Open-Label Study Designed to Evaluate the Pharmacokinetics, Safety, Tolerability, and Efficacy of a Simplified Dosing Regimen of Preveon® (Adefovir Dipivoxil, bis-POM PMEA), Videx® (Didanosine, ddI), Sustiva® (Efavirenz, DMP 266), and Epivir® (Lamivudine, 3TC) Administered Once a Day for the Treatment of HIV Infection

Type of treatment:

ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Adefovir dipivoxil: antiretroviral, reverse transcriptase inhibitor, nucleotide analog
DMP 266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if this four-drug combination is safe. well-tolerated and effective in lowering the amount of HIV in the blood of HIV-positive patients. To see how these four drugs are processed by the body.

About the study:

All patients will take Preveon® (adefovir dipivoxil), Videx® (ddI), Sustiva® (efavirenz, DMP 266), and 3TC. There are no placebos in this study. All medications are taken by mouth. Patients who do not show an adequate decrease in the amount of HIV virus in the blood will be discontinued from the study. Study visits are every two weeks for the first month, then once a month until the end of the study. The study lasts about one year and patients who have completed 48 weeks of treatment will be able to continue receiving Preveon® until it is FDA-approved and commercially available in the United States.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 5,000 copies/mL
- HIV positive
- At least 13 years old

Not allowed:

- Prior use of any NNRTIs, such as delavirdine, nevirapine or Sustiva®
- Prior use of adefovir dipivoxil (Preveon®), ddI or 3TC
- Women who are pregnant or breastfeeding

Location:

Pacific Oaks Research Group
Donna Morales, RN
(310) 360-8800

New

14. HIV Infection: T-20

Title:

TRI-003: A Phase II Evaluation of the Safety, Plasma Pharmacokinetics, and Antiviral Activity of T-20 Administered to HIV-1 Positive Adults by Continuous Subcutaneous Infusion

Type of treatment:

T-20: antiretroviral, fusion inhibitor

Purpose:

To see if T-20 is safe and effective in treating HIV infection. To see how T-20 is processed by the body.

About the study:

Patients are assigned by chance to receive one of four doses of T-20 by continuous infusion under the skin or to receive one of two doses of T-20 by injection under the skin. All patients will receive medication every day for 28 days. Patients assigned to continuous subcutaneous infusion will have a small plastic tube placed under their skin using a small needle. After the tube is in place, the needle is removed. Patients will need to have this tube changed every day. On Days 0, 1 and 14, patients will remain at the clinic all day and on Days 0 and 14, have multiple blood draws. The study lasts seven weeks and patients will be paid for their participation.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 5,000 copies/mL
- HIV positive
- At least 18 years old
- Patients on antiretroviral therapy must be on stable (no changes) therapy for at least six weeks prior to study entry

Not allowed:

- Active opportunistic infections
- Fever of at least 38.5 C or 101.3 F for seven consecutive days within 30 days of study entry
- Chronic diarrhea, defined as more then three liquid stools per day which persists for 15 days, within 30 days of study entry
- Any cancers other than KS of the skin, cervical cancer, or basal cell carcinoma of the skin
- Hemophilia or other blood clotting disorders
- Women who are pregnant or breastfeeding
- Active alcohol and/or substance abuse

Location:

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

New

15. HIV Infection: Thalidomide

Title:

Virologic, Pharmacokinetic, Immunologic, and Endocrine/Metabolic Effects of Thalidomide in HIV-Seropositive Subjects

Type of treatment:

Thalidomide: cytokine inhibitor, antiwasting

Purpose:

To see what effect thalidomide has on HIV viral load in patients who are on stable (no changes) protease inhibitor therapy. To see the interaction of thalidomide and protease inhibitors and how they are processed by the body. To see what effects thalidomide has on the immune system and on body metabolism.

About the study:

Patients are assigned by chance to receive thalidomide or placebo for four weeks. Thalidomide and its placebo are pills and taken by mouth. Neither patients nor their doctors will know which they are taking until the study ends. At the beginning of the study and after four weeks, patients will be admitted to the research center for two days of blood tests, metabolic tests, body weight and composition. Study visits are once a week and patients will attend a final study visit one month after the four-week treatment period is completed. The study lasts two months and **patients will be paid $850 for completing the study.**

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: stable for the past four weeks
- Stable (no changes) antiretroviral therapy with at least three medications, one being a protease inhibitor, for at least four weeks prior to study entry and throughout the duration of the four-week treatment period
- Women of childbearing potential must commit either to refrain from reproductive sexual intercourse **OR** to practice **TWO** methods of contraception, one barrier and one hormonal
- Body mass index less than 28 kg/m2

Not allowed:

- Women who are pregnant or breastfeeding
- Use of thalidomide within six weeks of study entry
- Current severe peripheral neuropathy
- Any vaccinations within the past six weeks

Location:

UCSF/SFGH Endocrinology
Clara Shayevich, NP
(415) 206-4368

New

16. HIV Infection: WF10

Title:

WF10-97-US-004: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Pivotal Clinical Study Evaluating the Safety and Efficacy of WF10 (TCDO) Intravenous Solution in the Management of Patients with Late-Stage HIV Disease

Type of treatment:

WF10 (TCDO): immune modulator

Purpose:

To see if WF10 has any effect on the survival of patients with late-stage HIV disease. To see if WF10 has any effect on disease progression and on the quality of life.

About the study:

Patients are assigned by chance to receive WF10 or placebo (saline). WF10 and placebo are given by infusion into a vein for five consecutive days followed by 16 days of rest (one cycle). Patients will receive four consecutive cycles of treatment. The treatment period lasts eleven weeks. Study visits are at Week 18, then every three months starting at Week 24 and lasting through the first year. Study visits are every six months during the second year. The study lasts for two years.

Required:

- CD4 cell (T-cell) range: 50 or less
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Must have stable (no changes) antiretroviral treatment for at least 30 days prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Current use of Interleukins, interferons, G-CSF, GM-CSF, immunoglobulins, cyclosporins or methotrexate
- Any cancers requiring chemotherapy

Location:

Center for Special Immunology - Irvine
Sandra Casserella, RN
(949) 753-0670

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

17. HIV Infection in Under-Represented Populations: Abacavir, Combivir™

Title:

NZTA 4006: A Phase IIIB Open-Label, Randomized Study of the Effect of an Educational Intervention on Virologic Outcomes, Adherence, Immunologic Outcome and Health Outcomes in HIV-Infected Subjects From Under-Represented Populations Treated with Triple Nucleoside Therapy (Combivir, Lamivudine 150mg/Zidovudine 300mg, PO BID Plus Abacavir 300 mg PO BID)

Type of treatment:

Combivir: antiretroviral, nucleoside analog
1592U89: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if an educational intervention program called Tools for Health and Empowerment Course (T.H.E.) has any impact on HIV viral load, patient adherence, immunologic response and health outcomes on patients from under-represented populations (ethnic minorities, women, injection drug users).

About the study:

All patients will take abacavir (also called 1592U89 or Ziagen™) and Combivir™, a fixed dose tablet of AZT and 3TC. There are no placebos in this study. Patients are assigned by chance to an educational program called T.H.E. (Tools for Health and Empowerment) Course plus routine counseling or to receive routine couseling by itself. Abacavir and Combivir™ are pills taken twice a day. The pills are provided in a package equipped with an electronic monitoring device to record the date and time that each medication dose is punched out of the package. Patients will take medications for 24 weeks. The T.H.E. educational program consists of two-hour interactive sessions once a week for the first four weeks for patients and informal caregivers. Educational methods include interactive group discussions, workbooks, reference books, videos and overhead projections. The study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: more than 40 copies/mL but less than 100,000 copies/mL
- HIV positive
- At least 18 years old
- Either no prior use of antiretrovirals or no more than six months total use of antiretrovirals. Must have no experience with either AZT **OR** 3TC

Not allowed:

- Prior use of any protease inhibitors, NNRTIs, such as delavirdine or nevirapine, or Sustiva® (DMP 266)
- AIDS diagnoses other than T-cell counts of less than 200
- Active alcohol and/or substance abuse
- Patients who are unlikely to attend the four T.H.E. Course sessions, in the opinion of the research staff
- Women who are pregnant or breastfeeding
- Active or chronic hepatitis
- Use of radiation or chemotherapy within four weeks of study entry or the need for such throughout the study
- Use of any immunomodulators, such as interleukins, interferons, corticosteroids or vaccines within four weeks of study entry

Location:

AIDS Healthcare Foundation
Eung Kim
(213) 913-3953

18. HIV Infection in Women: Viracept®, Invirase™, 3TC, d4T

Title:

AG1343-534: Phase II, Randomized Study of the Safety and Efficacy of Viracept® (BID) and Saquinavir (BID) Administered in Combination with Stavudine (d4T) and Lamivudine (3TC) Versus Viracept® (TID) and Saquinavir (TID) Administered in Combination with Stavudine (d4T) and Lamivudine (3TC) in HIV-Positive Women

Type of treatment:

Invirase™: antiretroviral, protease inhibitor
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To see how Viracept® and saquinavir (Invirase™), in combination with d4T and 3TC, are processed by womens' bodies. To see if these combinations are safe and effective for HIV-positive women to take. To observe gynecological events associated with HIV disease

About the study:

All women will receive 3TC and d4T and will be assigned by chance to receive one of two doses of Viracept® and saquinavir. Patients will know which doses of Viracept® and saquinavir they are taking. All medications are pills and taken by mouth. Study visits are every two weeks for the first month, then once a month. A cervical lavage and pap smear will be performed during this study. The study lasts one year.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 10,000 copies/mL
- HIV positive
- Female patients only
- At least 13 years old
- Must be antiretroviral naive or have less than one month cumulative exposure to d4T and/or 3TC

Not allowed:

- Male patients
- Prior use of any antiretrovirals. Less than one month cumulative use of d4T and/or 3TC is allowed
- Prior use of any protease inhibitors
- Use of any immune modulators or vaccines within one month of study entry
- Any cancers requiring chemotherapy or radiation therapy or any use of such treatments within one month of study entry
- Acute pancreatitis or hepatitis
- Past episode(s) of bilateral peripheral neuropathy
- Women who are pregnant or breastfeeding
- Active alcohol or substance abuse

Location:

LAC-USC Medical Center ACTU
Hannah Edmondson-Melancon, RN
(323) 343-8280

19. HIV Infection: 1592U89 (abacavir, Ziagen™)

Title:

CNAA-B3008B: A 1592U89 Open Label Protocol for Adult Patients with HIV Infection

Type of treatment:

1592U89: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To provide 1592U89 to patients who have limited treatment options.

About the study:

All patients will receive 1592U89. Patients must be seen by their doctors at month 1, month 3 and every three months thereafter for data collection. Patients will be in this study until their doctors feel they are no longer receiving benefits or until the drug is FDA-approved and marketed in the United States.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- At least 13 years old
- HIV positive
- Patients who are failing or intolerant of standard therapy and cannot construct a treatment plan without abacavir

Not allowed:

- Women who are pregnant or breastfeeding
- Active alcohol or substance abuse
- Current liver or kidney failure, diabetes, congestive heart failure, cardiomyopathy or other cardiac dysfunction

Location:

AltaMed HIV Services
Monica Lopez
(323) 869-5429

Center for Special Immunology - Irvine
Sandra Casserella, RN
(949) 753-0670

Kaiser Permanente - Los Angeles
Rosa Kawahira, RN
(213) 783-8172

Kraus Medical Partners
Stanka Derzic
(213) 930-2324

Sherman Oaks Hospital Research Institute
Monica Medina
(818) 205-1902

20. HIV Infection: Adefovir Dipivoxil (Preveon®)

Title:

GS-97-423: The Preveon® (adefovir dipivoxil) Expanded Access Program for the Treatment of Patients with AIDS Who Have Failed Other Antiretroviral Therapy and Have Limited Treatment Options

Type of treatment:

Adefovir dipivoxil: antiretroviral, reverse transcriptase inhibitor, nucleotide analog

Purpose:

To make Preveon® available to patients who have failed combination therapy and have limited remaining treatment options. To make Preveon® available to patients who have received Preveon® through participation in a Gilead-sponsored clinical study who may benefit from continued treatment with Preveon®.

About the study:

All patients will receive Preveon® and L-carnitine which are taken by mouth once a day. Patients must be seen by their doctors at least once a month for data collection. Patients will be in this study until patients can no longer tolerate the treatment or until Gilead Sciences terminates the study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 13 years old
- Failure (as defined by T-cell counts and viral load) or intolerance of combination therapy consisting of at least two NRTIs (AZT, 3TC, ddI, ddC, d4T) and at least one protease inhibitor
- Physician is unable to put together a suitable combination based on current guidelines and patient's previous antiretroviral use

Not allowed:

- Women who are pregnant or breastfeeding

Location:

AltaMed HIV Services
Monica Lopez
(323) 869-5429

Center for Special Immunology - Irvine
Sandra Casserella, RN
(949) 753-0670

Kraus Medical Partners
Marsue Davidson, RN
(213) 930-2324

Sherman Oaks Hospital Research Institute
Vicky Ramirez
(818) 205-1902

21. HIV Infection: CSF Viral Load

Title:

Cerebrospinal Fluid Analysis of HIV-1 Viral Burden in HIV-1-Infected Subjects: Response to Antiretroviral Therapy

Type of treatment:

Observational: none

Purpose:

To see what effect antiretroviral therapy has on the amount of HIV in the spinal fluid and to see what effect it has on neurological function.

About the study:

Patients in this study will have two lumbar punctures (spinal taps) at the beginning of the study and three more spinal taps during the course of one year. Spinal taps consist of a needle being passed into the spinal column between vertebra and having some fluid removed. Patients are paid $75 for the first spinal tap, $100 for the second, and $125 for the next three. Blood tests and neurological exams will also be performed at weeks 16 and 52. The study lasts one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Patients must be starting or changing antiretroviral therapy at the time of study entry

Not allowed:

- Brain mass lesions
- Neurological disorders such as cryptococcal meningitis, toxoplasmosis, severe psychiatric disorder or active drug or alcohol abuse
- Noncompliance with antiretroviral medications

Location:

SFGH Department of Neurology
Richard W. Price, MD
(415) 206-3208

22. HIV Infection: Combivir™, Abacavir (1592U89)

Title:

SFGH002: Fixed Dose Combination Zidovudine/Lamivudine Plus Abacavir as a Maintenance Regimen for Subjects with Long-Term HIV-1 Supression

Type of treatment:

1592U89: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Combivir™: antiretroviral, nucleoside analog

Purpose:

To see if Combivir™ plus abacavir is effective in maintaining undetectable HIV viral load levels in patients who have achieved undetectable HIV viral load levels after at least six months of highly aggressive antiretroviral therapy (HAART).

About the study:

Patients are assigned by chance to take the fixed dose tablet of AZT and 3TC, called Combivir™, plus abacavir (1592U89) **OR** remain on their current combination therapy. Both Combivir™ and abacavir are pills and taken by mouth twice a day. Study visits are every two weeks and the study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: more than 200
- Viral load range: less than 100 copies/mL
- HIV positive
- Between 18 and 65 years old

Not allowed:

- Use of 3TC as monotherapy or in combination with any other nucleoside analogs (such as AZT, d4T, ddI, ddC) unless taken along with a protease inhibitor

- Any past or current opportunistic infections, other than KS of the skin
- Use of any immunomodulators, such as interferons or interleukins, within four weeks of study entry
- Women who are pregnant or breastfeeding

Location:

UCSF AIDS Program at SFGH/ICTG
Dorie Heeren, RN
(415) 476-9296, ext. 305

23. HIV Infection: Cyclosporin

Title:

ACTG 334: Phase II Study of Cyclosporin (Neoral) in Immune Activation and HIV Expression in Early HIV Disease

Type of treatment:

Cyclosporin: immune suppresant

Purpose:

To see if cyclosporin (Neoral) is safe to take for persons with HIV infection.

About the study:

Patients are assigned by chance to receive Neoral (cyclosporin) or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. Some patients will be allowed to take one of four antiretroviral combinations; others will not be allowed to take any anitretroviral therapy at all. Neoral and its placebo are pills and taken by mouth. Patients will take study medication every day for twelve weeks. Study visits are every two weeks for the first two months, then once a month. Patients will have blood samples drawn and skin tests performed at study visits. The study lasts 16 weeks.

Required:

- CD4 cell (T-cell) range: at least 500
- Viral load range: more than 600 copies/mL
- HIV positive
- At least 18 years old
- Either no antiretroviral therapy for at least four weeks prior to study entry **OR** at least eight weeks of stable (no changes) therapy with either AZT plus 3TC; AZT plus ddI; d4T plus 3TC; or d4T plus ddI

Not allowed:

- Past or current AIDS-defining conditions
- Prior use of NNRTIs, such as delavirdine, nevirapine or DMP-266
- Prior use of any protease inhibitors
- Women who are pregnant or breastfeeding
- History of hypertension; systolic > 140/diastolic >90
- Currently taking any other investigational drugs

Location:

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

24. HIV Infection: Cyclosporin

Title:

A Pilot Study of Cyclosporin-A in Modulating Immune System Activation in HIV-1 Disease

Type of treatment:

Cyclosporin: immune suppresant

Purpose:

To see if cyclosporin is safe and to see if it can help to lower the immune system activation that accompanies HIV disease.

About the study:

All patients will receive cyclosporin. Cyclosporin is a pill and taken by mouth. After four weeks, patients will take a higher dose for another four weeks. Study visits are once a week and the study lasts 12 weeks. **Patients wil be paid $40 for each study visit completed**

Required:

- CD4 cell (T-cell) range: between 300 and 600
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Patients on antiretroviral therapy must discontinue use for at least 30 days prior to study entry and throughout the study

Not allowed:

- No exclusions

Location:

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

25. HIV Infection: Delavirdine, Indinavir, AZT, 3TC

Title:

M/3331/0074: An Open Label Study of Delavirdine Mesylate in Triple and Quadruple Combinations with Zidovudine, Indinavir and Lamivudine in HIV-Infected Individuals

Type of treatment:

Indinavir: antiretroviral, protease inhibitor
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Delavirdine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To test the safety, tolerability and effectiveness of combinations of three or four drugs.

About the study:

Patients are assigned by chance to one of four groups: delavirdine + indinavir + AZT; delavirdine + indinavir + 3TC; delavirdine + indinavir + AZT + 3TC; indinavir + AZT + 3TC. Patients in three of the groups will be taking three medications while patients in the fourth group will be taking four. Patients will know which medications they are taking. All medications are pills and taken by mouth. Study visits are once a week for the first month, then once a month for two months, then every two months. The study lasts 24 weeks and patients may choose to continue for another 24 weeks. Some locations may pay patients for their participation.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: at least 20,000 copies/mL
- HIV positive
- At least 14 years old

Not allowed:

- More than six months use of AZT
- Prior use of 3TC or any NNRTIs, such as delavirdine, nevirapine, DMP-266, atevirdine, loviride or HBY 097
- Prior use of any protease inhibitors
- Use of any investigational drugs or immunomodulators, such as interferons or interleukins, within 21 days of study entry
- Use of any HIV vaccines within 21 days of study entry
- Active opportunistic infections within one month of study entry
- Use of rifampin or rifabutin within 21 days of study entry
- Use of Hismanal, Seldane, Xanax, Halcion or Propulsid within 7 days of study entry and throughout the study
- Women who are pregnant or breastfeeding
- Active alcohol or substance abuse
- Cirrhosis of the liver

Location:

UC Irvine Medical Center
Beth Michel, RN
(714) 456-7612

UCSF AIDS Program at SFGH/ICTG
Anna Smith, RN
(415) 476-9296, ext. 313

26. HIV Infection: Delavirdine, Nelfinavir, ddI, d4T

Title:

M/3331/0073: An Open Label Randomized Study of Delavirdine Mesylate Plus Nelfinavir, Didanosine and Stavudine in Triple and Quadruple Treatment Regimens in HIV-Infected Individuals

Type of treatment:

Delavirdine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
Nelfinavir: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To test the safety, tolerance and effectiveness of combinations of three or four drugs.

About the study:

Patients are assigned by chance to one of four groups: delavirdine + nelfinavir + d4T; delavirdine + nelfinavir + ddI; delavirdine + nelfinavir + d4T + ddI; delavirdine + d4T + ddI. Patients in three of the groups will be taking three medications while patients in the fourth group will be taking four. Patients will know which drugs they are taking. All medications are pills and taken by mouth. Study visits are once a week for the first month, then once a month for two months, then every two months. The study lasts 24 weeks and patients may choose to continue for another 24 weeks.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: at least 20,000 copies/mL
- HIV positive
- At least 14 years old

Not allowed:

- More than six months total use of ddI
- Prior use of d4T or any NNRTIs, such as delavirdine, nevirapine, DMP-266, atevirdine, loviride or HBY 097
- Prior use of any protease inhibitor
- Use of any investigational drug or immunomodulators, such as interferons or interleukins, within 21 days of study entry
- Use of any HIV vaccines within 21 days of study entry
- Active opportunistic infections within one month of study entry
- Use of rifampin or rifabutin within 21 days of study entry
- Use of Hismanal, Seldane, Xanax, Halcion or Propulsid within 7 days of study entry and throughout the study
- Women who are pregnant or breastfeeding
- Active alcohol or substance abuse
- Cirrhosis of the liver

Location:

UC Irvine Medical Center
Beth Michel, RN
(714) 456-7612

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

ViRx, Inc. - Palm Springs
Tom Clover, RN
(760) 864-6266

27. HIV Infection: FP-21399

Title:

A Phase II Trial of FP-21399 in Patients With HIV Infection on Stable Antiviral Therapy Without Complete Viral Suppression

Type of treatment:

FP-21399: fusion inhibitor

Purpose:

FP-21399 is a new antiretroviral that works in a different way than any other approved antiretrovirals. FP-21399 seeks out the lymph nodes and appears to remain there for extended periods of time. The purpose of this study is to see if FP-21399 is safe and well-tolerated and if it has any effects on immune function in HIV patients.

About the study:

All patients will receive FP-21399; there are no placebos in this study. FP-21399 is given by infusion into a vein every four weeks. There is a baseline/screening period of four weeks, then study visits are once a month. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: 200 or less
- Viral load range: more than 10,000 copies/mL
- HIV positive
- At least 18 years old
- Stable (no changes) antiretroviral therapy for at least eight weeks prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Active opportunistic infections

Location:

St. Luke Medical Group & Clinical Trials
Rebecca Gonzalez
(619) 235-4211

28. HIV Infection: Fortovase™, Nelfinavir

Title:

NR15520B: A Randomized Phase IIIB Comparative Study to Evaluate Saquinavir Soft Gel Capsule (SGC) TID Regimen in Combination with Two NRTIs Versus Saquinavir Soft Gel Capsule (SGC) BID Regimen in Combination with Two NRTIs Versus Saquinavir Soft Gel Capsule (SGC) BID Plus Nelfinavir BID Plus an NRTI in HIV-1 Infected Patients

Type of treatment:

Fortovase™: antiretroviral, protease inhibitor
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To see how effective treatment with saquinavir soft gel capsules (Fortovase™) is at lowering HIV RNA load when used in three different dosages and drug combinations.

About the study:

Two different types of patients will be enrolled: antiretroviral experienced (persons with at least three months prior antiretroviral therapy) and antiretroviral naive (persons with no prior use of antiretrovirals). Patients are assigned by chance to one of three treatment groups. The first group will take saquinavir soft gel capsules (Fortovase™) three times a day plus two new nuceloside analogs, such as AZT, 3TC, d4T, ddI, or ddC. The second group will take saquinavir soft gel capsules (Fortovase™) twice a day plus two new nucleoside analogs. The third group will take saquinavir soft gel capsules (Fortovase™) twice a day plus nelfinavir (Viracept®) twice a day plus a new nucleoside analog. The antiretroviral(s) assigned will be "new" to the patient (no prior use). For experienced patients entering into groups 1 or 2 who have used four of the five antiretrovirals, the second assigned antiretroviral will be one used in the distant past. All patients will know which medications they are receiving. There are no placebos in this study. Study visits are once every two weeks for the first month; then once each month until 24 weeks, and then every two months until the end of the study at about one year. Some study sites may pay patients for their participation.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 5,000 copies/mL
- HIV positive
- At least 16 years old
- For antiretroviral-experienced patients, more than three months of therapy with nucleoside analogs (AZT, 3TC, d4T, ddI, ddC)

Not allowed:

- More than two weeks of treatment with any protease inhibitors
- Prior use of any NNRTIs, such as nevirapine or delavirdine
- Women who are pregnant or breastfeeding

Location:

Kaiser San Francisco - HIV Research Unit
Barbara LeMaire, RN, MS
(415) 202-3486

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

Quest Clinical Research, San Francisco
Eileen Glutzer, RN
(415) 353-0800

Sherman Oaks Hospital Research Institute
Monica Medina
(818) 205-1902

St. Luke Medical Group & Clinical Trials
Rebecca Gonzalez
(619) 235-4211

29. HIV Infection: GM-CSF, Interleukin-12, AZT, 3TC, Indinavir, Nevirapine

Title:

ACTG 387: A Randomized Controlled Trial to Compare the Efficacy of a Four Drug Antiretroviral Regimen Alone or in Combination with GM-CSF or IL-12 Administered to HIV-1 Infected Subjects as Measured by the Characteristics of Viral Decay

Type of treatment:

Interleukin-12: immune modulator
Combivir™: antiretroviral, nucleoside analog
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
Indinavir: antiretroviral, protease inhibitor
GM-CSF: white blood cell stimulator

Purpose:

To look at the characteristics of early suppression of HIV in the blood and to see if taking GM-CSF or interleukin-12 helps to speed up the rate at which HIV is reduced in the blood.

About the study:

Patients are assigned by chance to one of two groups. Patients in **Group A** are admitted to the hospital for the first three days of the study and are assigned by chance to take Combivir™ (AZT/3TC fixed dose) **OR** nevirapine **OR** indinavir **OR** Combivir™ plus nevirapine plus indinavir. All medications will be given by mouth. Patients wil have multiple blood draws during the first three days of the study. After the frist three days, patients will leave the hospital and all patients will take Combivir™, nevirapine and indinavir. Patients in **Group B** will take Combivir™, nevirapine and indinavir and have blood drawn during the first week of the study. On Day 6, both groups will have blood drawn for tests over an eight-hour period. On Day 7, all patients are assigned by chance to receive CM-CSF or interleukin-12 to take in addition to the four study drugs or to receive no additional medications. GM-CSF is given by injection under the skin every day for two weeks, then three times a week through week 14. Interleukin-12 is given by injection under the skin twice a week through week 14. Patients assigned to take GM-CSF will be taught how to inject themselves at home. Patients assigned to receive interleukin-12 must come to the clinic twice a week for their injections. GM-CSF and interleukin-12 will be given through week 14 and then stopped and all patients will continue taking Combivir™, indinavir and nevirapine until the end of the study. Study visits are one a week for the first six weeks, then every other week through week 12, then once a month until the end of the study. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: at least 300
- Viral load range: at least 20,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- Any antiretroviral therapy taken for more than seven days
- Any antiretroviral treatment within 90 days of study entry
- Tested HIV positive less than six months prior to study entry
- Any active opportunistic infection
- Use of any immunomodulators or investigational drugs within 30 days of study entry
- Any immunization within 30 days of study entry
- Any cancers, including KS, which require chemotherapy
- New onset of unexplained fever (more than 38.5 C or 101.3 F) for any seven consecutive days
- Women who are pregnant or breastfeeding

Location:

UCSD Treatment Center
Screening Nurse
(619) 543-8080

30. HIV Infection: Genotypic Antiretroviral Resistance Testing (GART)

Title:

CPCRA 046: A Pilot Study of the Short-Term Effects of Antiretroviral Management Based on Plasma Genotypic Antiretroviral Resistance Testing (GART) Compared with Antiretroviral Management Without Plasma GART

Type of treatment:

Observational: none

Purpose:

To see the effects of doctors using genotypic antiretroviral resistance testing (GART) to manage patients' antiretroviral therapy.

About the study:

Patients are assigned by chance to one of two groups. The doctors treating patients in the first group will be given the results from GART and will use the results to make changes in their patients' antiretroviral therapy. Doctors treating patients in the second group will not be given the results from GART but will use current tests, such as CD4 cell count and HIV RNA viral load measurements to make decisions about changing their patients' antiretroviral medications. After two initial visits, study visits are once a month and the study lasts three months.

Required:

- CD4 cell (T-cell) range: between 50 and 500
- Viral load range: more than 50,000 copies by bDNA; more than 25,000 copies by PCR
- Must currently be on one of the following therapies for at least 16 weeks:
  AZT + 3TC + Indinavir
  AZT + 3TC + Saquinavir
  AZT + 3TC + Ritonavir
  d4T + 3TC + Indinavir
- HIV positive
- At least 13 years old
- At least 18 months of cummulative antiretroviral therapy
- Must have had a large rise in HIV RNA viral load or a previously documented HIV RNA level of undectectable while on current therapy (as above)

Not allowed:

- Patients unwilling or unable to change their antiretroviral therapy
- Any vaccination or illness within two weeks prior to study entry and throughout the study
- Patients who have had access to previous genotypic or phenotypic testing results

Location:

Community Consortium
Available at the locations listed on page 115
(415) 476-9554

31. HIV Infection: Indinavir, Efavirenz, Adefovir dipivoxil

Title:

Merck 075: A Multicenter, Open-Label Study of the Effect of Indinavir, Efavirenz and Adefovir Dipivoxil Combination Therapy in Patients Who Have Failed Nelfinavir

Type of treatment:

DMP 266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
Adefovir dipivoxil: antiretroviral, reverse transcriptase inhibitor, nucleotide analog
Indinavir: antiretroviral, protease inhibitor

Purpose:

To see if indinavir (Crixivan®) plus efavirenz (also called DMP 266 or Sustiva®) plus adefovir dipivoxil (also called bis-POM PMEA or Preveon®) is safe and effective for lowering HIV RNA to undetectable levels in patients who have never taken any protease inhibitors or who have had treatment failure with nelfinavir.

About the study:

All patients will receive indinavir, efavirenz and adefovir dipivoxil. There are no placebos in this study. All medications are pills and taken by mouth. Study visits are every two weeks for the first three visits, then once a month for the next three visits, then every two months for the remainder of the study. The study lasts one year.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: at least 10,000 copies/mL while taking nelfinavir
- HIV positive
- At least 16 years old
- At least 16 weeks of treatment with any NRTIs (such as AZT, ddI, ddC, 3TC. d4T)
- Naive to protease inhibitors or have failed treatment with nelfinavir

Not allowed:

- Prior use of any NNRTI (such as delavirdine, nevirapine, DMP 266) **or** adefovir dipivoxil
- Prior use of any protease inhibitor other than nelfinavir
- Women who are pregnant or breastfeeding
- Use of any immunomodulators (such as interleukins or interferons), G-CSF, or erythropoietin within 30 days of study entry
- Anticipated use of chemotherapy for any cancers during the study
- Active opportunistic infections or malignancies
- Active hepatitis
- Active alcohol or substance abuse

Location:

AIDS Community Research Consortium
Sharon O'Leary, RN
(650) 364-6563

LAC-USC Medical Center ACTU
Irene Teran, RN
(323) 343-8285

32. HIV Infection: Interleukin-12

Title:

ACTG 325: A Phase I Double-Blinded Trial of Recombinant Human Interleukin-12 (rhIL-12) in HIV-Infected Subjects With 300-500 CD4+ T Cells Who Have No Evidence of Serious Ongoing Opportunistic Infections

Type of treatment:

Interleukin-12: immune modulator

Purpose:

To see how well interleukin-12 is tolerated and to see if it is safe and effective in treating HIV infection. To find out which of three different doses of interleukin-12 is safest to take.

About the study:

Patients are assigned by chance to receive interleukin-12 or placebo. Interleukin-12 is given by injection under the skin. Injections are given twice a week. The study lasts four weeks.

Required:

- CD4 cell (T-cell) range: between 300 and 500
- Viral load range: not applicable
- Between 18 and 60 years old
- HIV positive
- Patients must have been on stable antiretroviral therapy for at least four weeks before study entry
- Must be willing to take drugs to prevent Pneumocystis carinii pneumonia (PCP) **(Part A only)**

Not allowed:

- Current antiretroviral therapy with ddC or d4T
- Past history of MAC, CMV or any invasive fungal disease (such as cryptococcosis, histoplasmosis, coccidiomycosis, etc.)
- Any use of interleukin-12 within the past 24 weeks
- Women who are pregnant or breastfeeding

Location:

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

33. HIV Infection: Interleukin-2, HAART

Title:

ACTG 328: A Phase II Study of Intermittent rhIL-2 by Intravenous or Subcutaneous Administration in Patients with HIV Infection on Highly Active Antiretroviral Therapy (HAART) or HAART Alone

Type of treatment:

Interleukin-2: immune modulator

Purpose:

To find out which method of taking interleukin-2 (by injection under the skin or by infusion into a vein) in combination with highly active antiretroviral therapy works best to increase the number of CD4+ cells (T-cells) in the blood.

About the study:

All patients will receive highly active antiretroviral therapy, consisting of two nucleoside analogs and the protease inhibitor, indinavir (Crixivan®), for 12 weeks. After ten weeks of antiretroviral therapy, patients will have a test to find out how much HIV virus is in their blood. Patients with more than 5,000 copies/mL of HIV virus in their blood will not continue in the study. Patients with fewer than 5,000 copies/mL of HIV will be assigned by chance to continue to receive highly active antiretroviral therapy (HAART) by itself, or to add interleukin-2, taken either by injection under the skin or by infusion into a vein. interleukin-2 is given in "cycles", consisting of five days of daily therapy every two months. If patients who receive interleukin-2 by infusion experience a substantial increase in their CD4+ cells (T-cells), they will receive interleukin-2 by injection under the skin for the remainder of the study. Study visits are approximately once a month at the beginning of the study, and then every two months later on. The entire study lasts 21 months.

Required:

- CD4 cell (T-cell) range: between 50 and 300
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Must be able to start taking either AZT + 3TC; AZT + ddI; d4T + 3TC; or d4T + ddI

Not allowed:

- Past or current AIDS-defining illnesses, except minimal Kaposi's sarcoma
- Any prior use of interleukin-2 or any protease inhibitors
- Use of corticosteroids, interferons, interleukins, thalidomide, GM-CSF, DNCB, thymopentin, Iosprinosine, Ampligen or Imuthiol within four weeks of study entry
- Women who are pregnant or breastfeeding
- Any cancers requiring treatment. Radiation therapy is allowed
- Active substance abuse that could interfere with the study

Location:

Harbor-UCLA Medical Center
Sandra Houston, LVN
(310) 222-5291

LAC-USC Medical Center ACTU
Hannah Edmondson-Melancon, RN
(323) 343-8280

Stanford University Medical Center
Sandra Valle, PA-C
(650) 723-8169

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF AIDS Program at SFGH/ACTU
David Rhodes, RN
(415) 476-9296 ext. 353

34. HIV Infection: Interleukin-2, HAART

Title:

MA9801: A Study of the Safety and Efficacy of Low-Dose Interleukin-2 (IL-2) in Combination With Highly Active Antiretroviral Therapy in Patients With CD4+ T-Cell Counts of Less Than 200 cells/mm^3

Type of treatment:

Interleukin-2: immune modulator
HAART: antiretrovirals, including at least one protease inhibitor

Purpose:

To observe changes in CD4 cells (T-cells) and HIV viral load in patients taking low-dose interleukin-2 with highly active antiretroviral therapy (HAART) for six months.

About the study:

Patients are assigned by chance to receive their current HAART alone or their current HAART with low-dose interleukin-2. Patients will know which treatment they are receiving. Interleukin-2 is given by injection under the skin once a day for six months. Patients assigned to interleukin-2 must come to the clinic every two weeks to pick up their medication. Study visits are at weeks 1, 4, 8, 16 and 26. The study lasts six months with a six month extension during which all patients will be offered HAART and interleukin-2.

Required:

- CD4 cell (T-cell) range: less than 200
- Viral load range: less than 500 copies/mL on two occasions within six months, one of the occasions within two months of study entry
- HIV positive
- At least 13 years old

Not allowed:

- Active AIDS-defining illnesses, except minimal KS of the skin
- Use of any immunomodulators, such as interleukins, interferons, or corticosteroids within four weeks of study entry
- Prior use of interleukin-2
- Use of rifampin or rifabutin within seven days of study entry
- Cancers requiring chemotherapy. Local radiation therapy is allowed
- Women who are pregnant or breastfeeding
- Any alcohol and/or substance abuse within the past five years
- Diabetes mellitus
- Need for transfusions of red blood cells or whole blood

Location:

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

New

35. HIV Infection: MKC-442

Title:

MKC-304: An Open Label Study of MKC-442 in at Least Triple Drug Combination in Patients Previously Treated With Nucleoside Reverse Transcriptase and Protease Inhibitors and Who Are Naive to Non-Nucleoside Reverse Transcriptase Inhibitors

Type of treatment:

MKC-442: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To see if MKC-442 is safe and effective when used in combination with other antiretroviral medications.

About the study:

Patients will take at least two or more antiretroviral medications by prescription and add MKC-442 to those drugs for 24 weeks. After 24 weeks, those patients who have a decrease in HIV RNA of 1.0 $\log_{10}$ or more may choose to continue taking MKC-442. Study visits are every two weeks for the first month, then once a month until week 24. The study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 5,000 copies/mL **following** treatment with a drug combination that included a protease inhibitor
- HIV positive
- At least 18 years old
- Can be given two or more antiretroviral medications by prescription based on medical history, medical condition, and prior use of antiretroviral drugs

Not allowed:

- Women who are pregnant or breastfeeding
- Prior use of any NNRTIs, such as delavirdine, nevirapine or Sustiva® (DMP 266)
- Severe diarrhea, defined as four or more watery stools per day for 15 days, within 30 days of study entry
- Use of radiation or chemotherapy within 30 days of study entry
- Active alcohol or substance abuse
- Current use of any experimental treatments

Location:

UCSF AIDS Program at SFGH/ICTG
Anna Smith, RN
(415) 476-9296, ext. 313

New

36. HIV Infection: MKC-442, Nelfinavir

Title:

MKC-303: A Randomized, Double-Blind Study of MKC-442 Combined with Viracept® in Patients Who are Protease Inhibitor and Non-Nucleoside Reverse Transcriptase Inhibitor Naive

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
MKC-442: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To see which drug combinations are best for reducing HIV RNA viral load levels to below detection (50 copies/mL) in six months.

About the study:

Patients are assigned by chance to receive MKC-442, a new non-nucleoside reverse transcriptase inhibitor (NNRTI), or placebo. Patients are also assigned by chance to one of two doses of Viracept® (nelfinavir). Neither patients nor their doctors will know which they are receiving until the study ends. All medications are pills and taken by mouth. Patients will also switch to one or two new NRTIs (such as 3TC, ddI, ddC, d4T) at the beginning of the study. Patients cannot take AZT while taking MKC-442. There is a study visit at Week 2, then once a month for the first six months (week 24), then once every two months until week 48. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 10,000 copies/mL
- HIV positive
- At least 18 years old
- At least 16 weeks prior experience with at least two nucleoside analogs (NRTIs)
- Must have no experience with at least one NRTI (AZT, 3TC, ddI, ddC, d4T)

Not allowed:

- Use of AZT while taking MKC-442
- Active AIDS-defining infections or conditions
- Prior use of any protease inhibitors or NNRTIs, such as delavirdine, nevirapine or DMP 266
- Women who are pregnant or breastfeeding
- Current alcohol or substance abuse
- Use of any immunomodulators, such as interferons or interleukins within 30 days of study entry
- Past or current pancreatitis
- Past or current severe peripheral neuropathy
- Use of radiation or chemotherapy within 30 days of study entry and throughout the study
- Chronic diarrhea

Location:

AltaMed HIV Services
Monica Lopez
(323) 869-5429

East Bay AIDS Center
Jeremy Swartzberg
Weena Joshi
(510) 204-2782

New

37. HIV Infection: MKC-442, Nevirapine, ddI, d4T, Hydroxyurea

Title:

ICC 601: A Phase II, 24-Week, Open-Label Study Designed to Evaluate the Pharmacokinetics, Safety, Tolerability and Efficacy of Novel Combination Therapy with Videx® (Didanosine), Zerit® (Stavudine), Viramune (Nevirapine) and MKC-442 (With or Without Hydroxyurea) for the Treatment of HIV-1 Infection in Non-Nucleoside Reverse Transcriptase Inhibitor-Naive Patients Who Failed Previous Protease Inhibitor Treatment

Type of treatment:

Hydroxyurea: cellular inhibitor
MKC-442: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To see if the four drug-combination of ddI, d4T, nevirapine and MKC-442 is safe, well-tolerated and has any effect on HIV viral load in patients who have failed previous protease inhibitor treatment.

About the study:

All patients will take ddI, d4T, nevirapine and MKC-442. There are no placebos in this study. All medications are taken by mouth. Patients will take these drugs for 12 weeks, at which time their viral load will be measured. Patients who show treatment failure at or after Week 12 may add hydroxyurea

to their drug combination. At Week 24, those patients who are showing a response to the medications may continue to receive study treatments. Study visits are every two weeks for the first month, then once a month until Week 24. Patients continuing after Week 24 will have study visits every twelve weeks. The study will last indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: between 5,000 and 50,000 copies/mL **after** six months of continuous protease inhibitor treatment
- HIV positive
- At least 18 years old
- Must be naive to **either** ddI **or** d4T

Not allowed:

- Prior use of MKC-442 or nevirapine
- Prior use of any other NNRTIs, such as delavirdine or DMP 266
- Women who are pregnant or breastfeeding

Location:

Pacific Oaks Research Group
Donna Morales, RN
(310) 360-8800

New

38. HIV Infection: MKC-442, d4T, ddI, Hydroxyurea

Title:

MKC-305: A Randomized, Double-Blind Study of MKC-442 Combined With Stavudine, Didanosine, and Hydroxyurea in HIV-Infected Patients Who Are Protease Inhibitor Experienced and Non-Nucleoside Reverse Transcriptase Inhibitor Naive

Type of treatment:

ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
MKC-442: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
Hydroxyurea: cellular inhibitor

Purpose:

To see if the combination of MKC-442, d4T, ddI and hydroxyurea is safe, well-tolerated and effective in lowering the amount of HIV in the blood.

About the study:

Two groups of patients will participate in this study. Patients in **Group A** have a viral load between 5,000 and 50,000 copies/mL and will take d4T, ddI and hydroxyurea. They will be assigned by chance to receive MKC-442 or placebo to take with these three medications. Neither patients nor their doctors will know which they are receiving until the study ends. Patients in **Group B** have more than 50,000 copies/mL of HIV and will take all four medications with no placebos. All medications are pills and taken by mouth. Patients assigned to placebo will be eligible for open label (real) MKC-442 after four weeks if they have less than a 1 $\log_{10}$ drop in viral load. Study visits are every two weeks for the first month, then once a month for five months, then every two months until the end of the study. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 5,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- Prior use of any NNRTIs, such as delavirdine, nevirapine or Sustiva®
- Women who are pregnant or breastfeeding
- Current use of any experimental medication
- Severe diarrhea, defined as four or more watery stools per day for 15 days, within 30 days of study entry
- Unable to eat due to chronic nausea/vomiting
- Chemotherapy or radiation therapy within 30 days of study entry
- Acute and clinically significant medical events within 30 days of study entry

Location:

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

39. HIV Infection: Marijuana, Marinol®

Title:

CC038/GCRC531: Short Term Effects of Cannabinoids in HIV Patients

Type of treatment:

Dronabinol: appetite stimulant
Marijuana: cannabinoid

Purpose:

To see if the interaction between cannabinoids and indinavir or nelfinavir can alter HIV RNA viral load. To measure the short-term effects of smoked marijuana on appetite, energy and body composition and body weight.

About the study:

Patients are admitted to the Research Center at San Francisco General Hospital for an initial four-day lead in period. During this time, patients will become accustomed to the Research Center and baseline measurements, such as T-cell counts, viral load, testosterone levels, expired carbon monoxide and body composition, will be obtained. Patients will then be asked if they wish to continue in the study. If so, patients are assigned by chance to receive marijuana cigarettes, Marinol® pills or placebo. Patients will not know if they are receiving Marinol® or placebo until the study ends. Marijuana cigarettes are smoked three times a day. Marinol® and its placebo are pills and taken by mouth three times a day. Patients will spend a total of 25 days and nights in the Research Center. The baseline measurements taken during the first four days will be repeated throughout the course of the hospital stay. After being discharged from the Research Center, patients will have two outpatient visits, one nine days after and the other three weeks after discharge from the hospital. Patients will be paid $1,000 for completing the study (or $20 per night if not completed).

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: must be stable (no drastic changes) for at least eight weeks prior to study entry
- Stable (no changes) antiretroviral medications for at least eight weeks
- Must have used marijuana in the past
- Must be taking indinavir (Crixivan®) or nelfinavir (Viracept®)

Not allowed:

- Active opportunistic infections or cancers requiring acute treatment
- Unintentional weight loss of more than 10% of body weight during the past six months
- Use of megace, nandrolone, oxandrolone, oxymetholone, DHEA, growth hormone, thalidomide, prednisone, interleukin-2, chemotherapy, radiation, other anabolic steroids or investigational agents within eight weeks of study entry
- Active alcohol and/or substance abuse
- Methadone maintenance
- Use of tobacco within 30 days of study entry
- Use of smoked marijuana within 30 days of study entry
- Pulmonary complications, such as asthma, tuberculosis, emphysema, cancer
- AIDS Dementia Complex (Stage II or higher)
- Women who are pregnant or breastfeeding

Location:

Community Consortium
Roz Leiser, RN
(415) 502-5705

40. HIV Infection: Nelfinavir, DMP 266, AZT, 3TC, Indinavir

Title:

ACTG 388: Phase III, Randomized Study of DMP 266 or Nelfinavir (NFV) in Combination with Zidovudine (ZDV), Lamivudine (3TC), and Indinavir (IDV) in HIV-Infected Patients with < 200 CD4 Cells/mm^3 or 100,000 HIV RNA Copies/mL or More

Type of treatment:

Combivir™: antiretroviral, nucleoside analog
DMP 266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
Nelfinavir: antiretroviral, protease inhibitor
Indinavir: antiretroviral, protease inhibitor

Purpose:

To compare two four-drug combinations with a three-drug combination for safety, tolerability and effectiveness in lowering the amount of HIV in the blood.

About the study:

All patients will take Combivir™ (a fixed-dose tablet of AZT and 3TC) plus indinavir. Additionally, patients are assigned by chance to take efavirenz (DMP 266) or nelfinavir in addition to Combivir™ plus indinavir or to take Combivir™ plus indinavir alone. All medications are pills taken by mouth and patients will know which medications they are taking. Patients will take study medications for a minimum of 72 weeks. Study visits are once a month for the first four months, then every two months for the remainder of the study. Patients may be asked to volunteer for substudies, smaller studies that are a part of the main study. The study lasts for about two years.

Required:

- CD4 cell (T-cell) range: 200 or less
  OR
- Viral load range: at least 100,000 copies/mL
- HIV positive
- At least 13 years old

Not allowed:

- Active opportunistic infections requiring treatment within 14 days of study entry
- Any cancers requiring chemotherapy
- Use of 3TC, NNRTIs (delavirdine, nevirapine, DMP 266), or protease inhibitors for more then one day
- Use of erythropoietin, G-CSF, GM-CSF, interleukins, interferons or HIV vaccines within 30 days of study entry
- Women who are pregnant or breastfeeding

Location:

Harbor-UCLA Medical Center
Sadia Shaik, MBBS
(310) 222-5291

Kaiser Permanente - Los Angeles
Rosa Kawahira, RN
(213) 783-8172

LAC-USC Medical Center ACTU
Gil Clemente, RN
(323) 343-8284

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

Stanford University Medical Center
Sandra Valle, PA-C
(650) 723-8169

UCSD Treatment Center
Screening Nurse
(619) 543-8080

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

UCSF AIDS Clinic
David Rhodes, RN
(415) 476-9296 ext. 353

41. HIV Infection: Nelfinavir, Ritonavir

Title:

CPCRA 042: A Randomized Trial of the Efficacy and Safety of Nelfinavir Versus Ritonavir Added to Background Antiretroviral Nucleoside Therapy in HIV-Infected Individuals With CD4+ Cell Counts of 200/mm^3 or Less

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor

Purpose:

To compare nelfinavir to ritonavir when added to backround antiretroviral therapy in terms of delaying disease progression and to measure safety.

About the study:

Patients are assigned by chance to receive nelfinavir or ritonavir to take with their antiretroviral therapy. Patients who are not taking any antiretroviral therapy are eligible to join, although the use of protease inhibitors by themselves is not recommended unless there is no other alternative. Patients will be allowed to switch to the other protease inhibitor if they experience disease progression or cannot tolerate their assigned medication. Both nelfinavir and ritonavir are pills and taken by mouth. There will be a one-month study visit after the screening visit, then every four months thereafter. The study lasts at least 18 months.

Required:

- CD4 cell (T-cell) range: 200 or less
- Viral load range: not applicable
- HIV positive
- At least 13 years old

Not allowed:

- Prior use of any protease inhibitors other than saquinavir
- Severe AIDS dementia complex
- Women who are pregnant or breastfeeding
- Current use of protease inhibitors during the study

Location:

Community Consortium
Available at the locations listed on page 115
(415) 476-9554

42. HIV Infection: Nelfinavir, ddI, d4T, AZT, 3TC

Title:

A1454-148: A Randomized Study of the Long-Term Suppression of Plasma HIV RNA Levels by Triple Combination Regimens in Treatment Naive Subjects

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see which triple combination is safest, best tolerated and most effective in reducing HIV viral load to an undectable level and to maintain the viral load at undectable levels.

About the study:

Patients are assigned by chance to receive either nelfinavir (Viracept®) plus ddI plus d4T **OR** nelfinavir plus AZT plus 3TC. All patients will know which medications they are taking and there are no placebos in this study. All medications are pills and taken by mouth. Study visits are once a month for the first two months, then once every two months for the remainder of the study. The study lasts about 48 weeks

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: at least 2,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- More than four weeks of any nucleoside therapy or more than one week of any protease inhibitor therapy **and** any such therapy must be discontinued at least 14 days prior to study entry
- Use of chemotherapy or any other toxic treatment within three months of study entry or the need for such treatment throughout the study
- Active alcohol or substance abuse
- Women who are pregnant or breastfeeding
- Active opportunistic infections
- Diarrhea (defined as 6 or more loose stools/day for seven or more days) within 30 days of study entry
- Severe peripheral neuropathy
- Past or current pancreatitis
- Acute hepatitis within 30 days of study entry or current chronic hepatitis

Location:

Harbor-UCLA Medical Center
Sandra Houston, LVN
(310) 222-5291

Sherman Oaks Hospital Research Institute
Vicky Ramirez
(818) 205-1902

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

43. HIV Infection: Remune®

Title:

IRC 903: An Expanded Access Open-Label Protocol of Remune® in HIV-1 Infected Subjects

Type of treatment:

Remune®: immune modulator

Purpose:

To provide Remune®, an alternate therapy for HIV, to patients who have no comparable or satisfactory alternative drugs available.

About the study:

All patients will receive Remune®. Remune® is given by injection into a muscle in the shoulder every 12 weeks. Remune® will be provided by the study but patients and/or insurance companies will be responsible for study-required laboratory tests and office visits. Study visits are every 12 weeks patients will be in this study until Remune® is approved for marketing in the United States.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: 100,000 copies/mL or less
- HIV positive
- At least 18 years old

Not allowed:

- Use of any immunomodulators, such as interleukins or interferons, within 30 days of study entry
- Women who are pregnant or breastfeeding
- Acute, active AIDS-defining conditions within 30 days of study entry

Location:

Center for Special Immunology - Irvine
Sandra Casserella, RN
(949) 753-0670

44. HIV Infection: RevM10-HSC (Gene Therapy), Cyclophosphamide

Title:

104: A Study of Infused RevM10 Enhanced Blood Stem Cells (REVM10-HSC) in HIV-Infected Subjects Who Have Been Mobilized with G-CSF (simplified)

Type of treatment:

RevM10-HSC: gene therapy
Cyclophosphamide: chemotherapy

Purpose:

To see if it is safe and effective to give genetically altered blood cells with or without cyclophosphamide to patients in various stages of HIV infection.

About the study:

All patients will receive injections of G-CSF (Neupogen) under the skin for four days, followed by apheresis on the fifth day. Apheresis is a process by which blood is removed from the body from one arm, certain cells (called stem cells) are separated from the blood, and the remaining blood is returned to the body through a vein in the other arm. The RevM10 gene is then added to the stem cells and the genetically-altered stem cells are returned to the patient by infusion into a vein. There are two groups in this study. The first group of patients will receive the altered stem cells without the addition of cyclophosphamide, also called Cytoxan. Cytoxan

is believed to enable to altered stem cells to get into the bone marrow. If no bad side effects are seen in the first group, the second group of patients will receive an infusion of Cytoxan 48 hours prior to the infusion of their genetically-altered stem cells. Patients will be paid for their participation in this study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Patients on antiretroviral therapy must be on stable (no changes) doses for at least 30 days prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Past or current cancers
- Use of G-CSF, GM-CSF, interleukins, interferons, growth hormones or steroids within 30 days of study entry
- Any pheresis procedure within 90 days of study entry
- Treatment for opportunistic infections within 30 days prior to study entry
- Active alcohol and/or substance abuse
- Use of any investigational drug within 30 days of study entry

Location:

AIDS Community Research Consortium
Brian Camp, RN
(650) 364-6563

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

45. HIV Infection: S-1153, Nelfinavir, Indinavir, AZT, 3TC

Title:

9719T0322: A Phase I/II Study of the Potential Interaction Between S-1153 and the Protease Inhibitors Nelfinavir and Indinavir in HIV-1 Infected Adults Treated with 3TC and AZT (or d4T)

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
S-1153: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
Indinavir: antiretroviral, protease inhibitor

Purpose:

To see if S-1153 is safe and effective in treating HIV disease when used with a triple combination therapy consisting of Indinavir or Nelfinavir plus AZT (or d4T) and 3TC.

About the study:

All patients will take S-1153 with their triple combination therapy. S-1153 is a pill and taken by mouth along with meals or food. There are no placebos in this study. Patients should be able to provide their own antiviral drugs used in the study but will be provided by the study if necessary. Study visits are once a week and there are two 10-hour visits and three 4-hour visits during the study. The study lasts two months. **Patients will be paid $500 for completing this study.**

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: not applicable
- Between 18 and 70 years old
- HIV positive
- Stable (no changes) use of AZT (or d4T) and 3TC for at least 35 days and use of indinavir or nelfinavir for at least 28 days prior to study entry
- Patients with less than 200 T-cells must take medicine to prevent PCP

Not allowed:

- Women who are pregnant or breastfeeding
- Any active opportunistic infection
- Use of vaccines or immunomodulators, such as interelukins or interferons, within 60 days of study entry
- Use of any other antiretroviral other than AZT, 3TC, d4T, indinavir or nelfinavir within 30 days of study entry
- Any cancer requiring chemotherapy or radiation therapy within four weeks of study entry and throughout the study
- Patients with severe diarrhea, defined as more than five stools per day
- Active alcohol or substance abuse
- Patients requiring transfusions or receipt of blood products or growth factors (such as EPO, G-CSF, GM-CSF) within 30 days prior to study entry

Location:

HIVCare, Saint Francis Memorial Hospital
Mark Bowers
(415) 353-6215

46. Post-HIV Exposure Prevention:Combivir™, ddI, d4T

Title:

The Post-Exposure Prevention Program: Identification, Treatment and Follow-up of Patients Following Substantial HIV Exposure

Type of treatment:

d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Combivir™: antiretroviral, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see the effect of using antiretroviral drugs on individuals following exposure to HIV and to provide counseling to reduce subsequent HIV exposure.

About the study:

Following substantial HIV exposure, most individuals will receive either Combivir™ (AZT/3TC fixed dose) or ddI/d4T, based on the decision of the study clinician. There are no placebos in this study and individuals will know which medications they are taking. There are four study visits in the first five weeks, then two visits at six months, then two more visits at one year. The study lasts about one year. Patients will be paid for attending some study visits.

Required:

- High risk exposure to HIV, defined as: unprotected anal or vaginal intercourse; shared needles, accidental needlesticks

Not allowed:

- No exclusions

Location:

UCSF AIDS Program at SFGH/ICTG
PEP Hotline
(415) 502-5737

New

47. HIV Infection: Phenotype Testing

Title:

CCTG 575: A Randomized, Prospective, Clinical Strategy Study of the Utility of a HIV-1 Phenotypic Resistance Assay to Manage Antiretroviral Therapy in Patients With Measurable HIV-1 RNA

Type of treatment:

Observational: none

Purpose:

To see if phenotype testing is useful in detecting drug resistance and in the management of antiretroviral drug therapy in HIV-infected patients who have a detectable HIV viral load.

About the study:

Patients are assigned by chance to have their treatment plan based on the results of CD4 cell (T-cell) counts, viral load and phenotype testing **OR** to have their treatment plan based on CD4 cell (T-cell) counts, viral load and the best clinical judgement by their doctors. All patients will have a phenotype test performed during the study screening visit. For those patients who are assigned to have their treatment plan based on phenotype testing, the results of the test will be made available to the doctor. For those patients assigned to have their treatment based on best clinical judgement, the results of their phenotype test will not be available until the end of the study. Study visits are every two months and patients will be on this study for about one year.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: detectable (at least 400 copies/mL)
- At least 18 years old
- HIV positive
- Must be on antiretroviral therapy for at least six months prior to study entry, including the use of a single protease inhibitor for at least three months **OR** have never used a protease inhibitor

Not allowed:

- Acute opportunistic infections

Location:

Santa Clara Valley Medical Center
Carol Kemper, MD
(408) 885-4690

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

48. HIV Infection: Phenotype Testing

Title:

VIRA3001: An Open-Label Randomized Trial Comparing the Effect on Viral Load of Standard HIV Treatment Practice (Delayed Phenotyping) with Treatment Based on the Antivirogram™ (Immediate Phenotyping)

Type of treatment:

Observational: none

Purpose:

The Antivirogram™ is a blood test that indicates to which antiretroviral medications patients may be resistant. The version offered in this study tests resistance to AZT, 3TC, ddI, d4T, ddC, indinavir, saquinavir, nevirapine, ritonavir and nelfinavir. The results can predict which of these medications would most likely be beneficial for treating patients and can be used to assign individual treatments. The purpose of this study is to see if there is an advantage to using the Antivirogram™ compared to standard treatment practice (delayed phenotyping).

About the study:

Patients are assigned by chance to have their treatment plan based on the results of the Antivirogram™ **or** to have their treatment plan based on the best clinical judgment by their doctors. The screening process lasts six weeks and all patients will have the Antivirogram™ performed during that time. For those patients assigned to have their treatment based on results of the Antivirogram™ (immediate phenotyping), the results of the phenotyping will be made available to their doctor. For those patients assigned to have their treatment based on best clinical judgement (delayed phenotyping), the results of their phenotyping will not be available to their doctors until the end of the study. All patients will have a second Antivirogram™ performed at week 16. Study visits are once a week for the first two weeks, followed by a baseline visit approximately six weeks after screening, then at Weeks 2, 4, 8, 12 and 16.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 2,000 copies/mL
- At least 13 years old
- HIV positive
- Stable (no changes) antiretroviral treatment for at least one month prior to study entry
- Patients have taken at least two NRTIs, such as AZT, ddI, ddC, d4T, 3TC
- Patients must be taking one protease inhibitor for at least one month prior to study entry and have taken no other protease inhibitors

Not allowed:

- No protease inhibitor experience **or** treatment with two or more protease inhibitors
- Prior use of any NNRTIs, such as delavirdine, nevirapine or DMP 266
- Active opportunistic infections
- Any cancers requiring chemotherapy
- Severe peripheral neuropathy
- Prior phenotypic testing
- Active alcohol or substance abuse

Location:

AIDS Healthcare Foundation
Edwin Graham, RN
(213) 913-3953

AIDS Research Alliance
Corie Castro
(310) 358-2429

East Bay AIDS Center
Jeremy Swartzberg
Weena Joshi
(510) 204-2782

Marcus Conant, MD Clinical Research
Renata Berg, MD
(415) 759-4126

Pacific Oaks Research Group
Donna Morales, RN
(310) 360-8800

Sherman Oaks Hospital Research Institute
Vicky Ramirez
(818) 205-1902

49. HIV Infection: Stress Management

Title:

REIMH57223: Coping Effectiveness Trial of HIV+ Men: The Changes Project

Type of treatment:

Intervention, Natural History:

Purpose:

To identify and examine the most effective ways to handle the stress related to HIV disease, particularly in the changing environment created by new drug treatments. It is also believed that the research may provide some strong data to help improve HIV health care guidelines and policies.

About the study:

Participants are assigned by chance to one of three research groups. The first group of men will receive periodic check-in phone calls to survey their individual perspectives about the ongoing changes in the HIV epidemic, and then will attend a series of three stress management workshops. The second group will receive a 3-month stress management training program followed by a series of frequent booster sessions. The third group will receive the same 3-month stress management training program followed by less frequent booster sessions. Participants in groups and workshops will meet to talk about the stresses they feel as a result of being HIV positive today and share ways to cope more effectively. The study lasts one year. Patients will be paid from $90 to $120 for completing the study.

Required:

- CD4 cell (T-cell) range: more than 50
- HIV positive
- Gay men only
- At least 21 years old
- Must remain in San Francisco Bay Area for the next 12 months

Not allowed:

- No exclusions

Location:

UCSF Center for AIDS Prevention Studies
Changes Project
(415) 597-9169

50. HIV Viral Load: Observational

Title:

CC035: A Descriptive, Observational Study of the Natural History of the State of Undetectable HIV RNA Induced by Combination Antiretroviral Therapy

Type of treatment:

Observational: none

Purpose:

To collect data from patients who have had a drop in the HIV RNA viral load to undetectable levels. To observe viral load levels over time, changes in CD4 (T-cell) counts and to observe HIV-related illnesses.

About the study:

This is an information collection study. Patients will have data from their medical charts collected by research study staff. The data collected will include routine laboratory test results, medication dosages and frequencies, and HIV-related illnesses. Data will be collected every four months. During routine office visits, patients may be asked about their health and medications by research study staff. These questions will require about two to three minutes. The study lasts three years.

Required:

- HIV positive
- Documented viral load of at least 1,500 copies/mL prior to initiation or change in combination antiretroviral therapy **and** a documented viral load of less than 500 copies/mL within 120 days after initiating/changing therapy
- At least 13 years old

Not allowed:

- People planning to move away from the Bay Area

Location:

Community Consortium
Available at the locations listed on page 115
(415) 476-9554

51. HIV Viral Load: Observational

Title:

ACTG 891: The Impact of Intercurrent Illness on HIV Viral Load

Type of treatment:

Observational: none

Purpose:

To see how much and for how long HIV viral load changes during and after the onset of an acute illness. To see what factors, such as type of illness (bacterial, fungal, viral), CD4 (T-cell) count and antiretroviral treatment, are associated with increases in HIV viral load.

About the study:

Patients joining this study must already be enrolled in an ACTG antiretroviral therapy study. Patients will report to the study clinic when they have a fever due to an acute illness. Study visits (viral load tests) will be done twice at the time of the acute illness, three days later, then weeks 1, 2, 4, 8, 16, and 24 for a total of six months.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Must be enrolled in an ACTG antiretroviral study
- Must be on stable (no changes) antiretroviral therapy for at least eight weeks prior to study entry
- Must have a documented fever of >101 F during at least one of the two days prior to the day of screening and come to the clinic on the day of screening

Not allowed:

- Any change in antiretroviral therapy within eight weeks prior to study entry
- Patients taking interleukin-2

Location:

UCSD Treatment Center
Screening Nurse
(619) 543-8080

New

52. HIV Drug Resistance: Observational

Title:

AVG-US-03: An Epidemiological Prospective Survey to Assess the Prevalence of Drug Resistance in a Group of 200 HIV-Positive Antiretroviral Naive Patients

Type of treatment:

Observational: none

Purpose:

To see the extent of drug-resistant HIV virus in patients who have not yet taken any antiretroviral medicines.

About the study:

This study consists of a blood test for phenotype and genotype testing. Patients will sign a consent form, have a medical history interview and have their blood taken. Patients will also be questioned concerning their infecting partner, if known. Phenotype and genotype testing will also be offered to the presumed infecting partner who must also sign the informed consent in addition to the blood test. There are no follow-up visits in this study.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Antiretroviral naive

Not allowed:

- Prior use of any antiretroviral medications

Location:

AIDS Research Alliance
Corie Castro
(310) 358-2429

East Bay AIDS Center
Jeremy Swartzberg
Weena Joshi
(510) 204-2782

Marcus Conant, MD Clinical Research
Renata Berg, MD
(415) 759-4126

Pacific Oaks Research Group
Donna Morales, RN
(310) 360-8800

New

53. HIV-Associated Anemia: Procrit

Title:

PR97-29-010: The Effect of Procrit (Epoetin alfa) on the Quality of Life of HIV-Infected Patients

Type of treatment:

Erythropoietin: red blood cell stimulator

Purpose:

To see if Procrit (also called erythropoietin) can improve anemia caused by HIV or HIV medications. To see what effect Procrit has on the quality of life.

About the study:

Patients are assigned by chance to receive Procrit three times a week or once a week. Procrit is given by injection under the skin and patients will be taught how to give themselves injections. Patients will receive injections for up to sixteen weeks. After screening and baseline visits, study visits are every two weeks for the first month, then once a month until Week 8, then every two months.The study lasts 16 weeks. Patients will be paid **$25 for transportation costs** once enrolled.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Anemia, defined as hematocrit less than 36%
- Serum erythropoietin level of 500 or less
- Must be currently taking antiretroviral medications

Not allowed:

- Active, acute opportunistic infections
- Past or current uncontrolled high blood pressure
- Anemia due to iron deficiency, hemolysis or gastrointestinal bleeding
- Women who are pregnant or breastfeeding
- Chemotherapy within 30 days of study entry
- Current treatment with ganciclovir and/or interferons

Location:

AIDS Healthcare Foundation
Edwin Graham, RN
(213) 913-3953

New

54. HIV-Associated Anemia: Procrit

Title:

PR98-29-002: The Effect of Weekly Dosing Regimen of Procrit on the Quality of Life in the Treatment of Anemia in HIV-Infected Patients on Antiretroviral Therapy

Type of treatment:

Erythropoietin: red blood cell stimulator

Purpose:

To see if Procrit (erythropoietin) is effective in treating anemia and improving the qulaity of life in HIV-infected patients who are taking antiretroviral theapy.

About the study:

All patients will receive Procrit once a week. Procrit is given by injection under the skin. If a patient's hemoglobin does not increase by one gram/dL after four weeks, the dose of Procrit will be increased. Patients will receive Procrit for a maximum of 16 weeks. Patients will also take an iron supplement throughout the study. The study lasts 16 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 75 years old
- Hemoglobin of less than 11 grams/dL
- Blood erythropoietin level of less than 500 mU/mL
- On stable (no changes) antiretroviral therapy for at least four weeks prior to study entry

Not allowed:

- Active opportunistic infections or AIDS-defining illness

- Past or current uncontrolled high blood pressure (diastolic blood pressure >100 mmHg)
- Anemia caused by iron deficiency, hemolysis or gastrointestinal bleeding
- Women who are pregnant or breastfeeding
- Active alcohol and/or substance abuse
- Current treatment with ganciclovir and/or interferons

Location:

AltaMed HIV Services
Monica Lopez
(323) 869-5429

St. Luke Medical Group & Clinical Trials
Rebecca Gonzalez
(619) 235-4211

55. Aphthous Ulcer Treatment: Thalidomide

Title:

R002: A Double-Blind, Dose Comparison Trial of Thalidomide for the Treatment of Recurrent or Refractory Aphthous Stomatitis (RAS) in HIV-Infected Patients

Type of treatment:

Thalidomide: cytokine inhibitor, antiwasting

Purpose:

To see if thalidomide is safe and effective in treating oral aphthous ulcers and to see if thalidomide is safe and effective in preventing oral aphthous ulcers from coming back.

About the study:

Patients are assigned by chance to receive one of three doses of thalidomide for 28 days of treatment. Neither patients nor their doctors will know which dose they are receiving until the study ends. Thalidomide is a pill and taken by mouth at bedtime. Study visits are once a week during this treatment phase of the study. Patients who respond to treatment within 28 days will be eligible for the maintenance treatment portion of the study. These patients will be assigned by chance to receive thalidomide or placebo for up to one year or sooner if relapse occurs. Study visits will be once a month for this portion of the study. Patients who do not respond to four weeks of treatment, who discontinue the study due to treatment failure, or who relapse will have the option of receiving thalidomide under a compassionate use protocol. The study lasts about one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Must be receiving treatment with at least two antiretroviral medications, preferably one being a protease inhibitor, and antiretroviral therapy must have been stable (no changes) for at least four weeks prior to study entry and for at least four weeks into the study
- Biopsy-confirmed aphthous stomatitis (oral ulcer)
- Females of childbearing potential must refrain from sexual intercourse **OR** practice **TWO** methods of contraception; one barrier and one hormonal

Not allowed:

- Women who are pregnant or breastfeeding
- Positive oral culture for herpes simplex
- Use of corticosteroids within 14 days of study entry
- Severe peripheral neuropathy

Location:

Kaiser San Francisco - HIV Research Unit
Joseph Thatcher, RN, MSN
(415) 202-2529

UCSF Stomatology Clinical Center
Behnaz Cheikh, DDS
(415) 502-4691 **OR**
Deborah Greenspan, DSc, BDS
(415) 476-3080

56. Cervical Dysplasia Prevention: Isotretinoin

Title:

ACTG 293: A Randomized, Phase III Trial of Oral Isotretinoin versus Observation for Low Grade Cervical Dysplasia in HIV-Infected Women

Type of treatment:

Isotretinoin: skin cell growth stimulant

Purpose:

To see if oral isotretinoin is effective in preventing progression of mild dysplasia to more severe dysplasia by comparing the time to progression of Cervical Intraepithelial Neoplasia (CIN) I to CIN II, III or invasive cancer in patients receiving isotretinoin versus observation.

About the study:

Patients are assigned by chance to receive oral isotretinoin or to be observed. Isotretinoin is a pill and taken by mouth once a day for six months. Study visits are once a month for six months; then one visit at months 12 and 18. Some locations may pay patients for their participation.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Females only
- At least 13 years old
- Diagnosis of CIN I by cervical biopsy (done by research staff at the test site)

Not allowed:

- CIN II, III, or invasive cervical cancer
- Any cancer requiring systemic chemotherapy within three months prior to study entry
- Previous use of isotretinoin within three months prior to study entry
- Past topical treatment for genital warts within one month prior to study entry
- Past treatment for CIN II or III
- Pregnancy or breastfeeding

Location:

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

LAC-USC Medical Center ACTU
Hannah Edmondson-Melancon, RN
(323) 343-8280

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

57. Oral Candidiasis Prevention: Self-Care Intervention

Title:

Self-Care Intervention to Prevent Oral Candidiasis

Type of treatment:

Intervention, Self-Care:

Purpose:

To see if a program of dietary and oral hygiene instruction (PRO-SELF:CANDIDIASIS) is effective in increasing the time between episodes of oral candidiasis (thrush) in HIV-infected patients. To see if patients in the PRO-SELF:CANDIDIASIS program report a recurrence of oral thrush more accurately than HIV-infected patients not using the program.

About the study:

Patients are assigned by chance to participate in the PRO-SELF:CANDIDIASIS program of diet modification and intensive oral hygiene or not to be in this program. Study visits will be every two weeks and the study lasts six months. Nystatin vaginal tablets or a prescription for the patient's antifungal drug of choice (mycelex or fluconazole) will be provided to treat episodes of oral candidiasis that occur during the study. As part of the study, all patients will have their teeth professionally cleaned twice, once at the beginning and at the end of the study. Patients will be paid $155 for completing this study.

Required:

- HIV positive
- At least 18 years old
- Must have had at least one episode of oral candidiasis in the past

Not allowed:

- Continuous use of oral or systemic antifungal medications

Location:

UCSF Stomatology Clinical Center
Laurie MacPhail, DMD
(415) 476-1690

58. Oral/Esophageal Candidiasis Treatment: Itraconazole

Title:

ITR-USA-109: An Open-Label, Non-Comparative Trial of Itraconazole Solution for the Treatment of Patients with Oropharyngeal/Esophageal Candidiasis Nonresponsive to Fluconazole

Type of treatment:

Itraconazole: antifungal

Purpose:

To see if itraconazole oral solution is safe and effective for treating oral or esophageal thrush (candidiasis) for patients whose thrush did not get better when taking fluconazole. This study will also provide itraconazole to patients unable to participate in other trials.

About the study:

All patients entering this study will receive open-label (real) itraconazole once a day for four weeks. This form of itraconazole is a liquid and is swallowed. After four weeks, patients either stop taking the drug if their thrush has gotten worse, or continue for two more weeks. After six weeks, patients whose thrush has gone away will continue on a lower dose (three times a week) indefinitely. All others discontinue the drug.

Required:

- CD4 cell (T-cell) range: not specified
- At least 13 years old
- Oral and/or esophageal thrush (candidiasis)
- Must have failed fluconazole 200 mg/day for a minimum of two weeks

Not allowed:

- Women who are pregnant or breastfeeding
- Liver disease

Location:

Tower Infectious Diseases
Tim Jordan, RN
(310) 358-2300 ext. 114

59. Oropharyngeal Candidiasis Treatment: BMS - 207147

Title:

A1422-005: A Randomized, Double-Blind, Phase I/II Study of the Safety, Pharmacokinetics and Antifungal Effects of Single and Multiple Doses of BMS-207147 in HIV+ Patients With Oropharyngeal Candidiasis

Type of treatment:

BMS-207147: antifungal

Purpose:

To see if a new drug, BMS-207147, is safe and effective for the treatment of oropharyngeal candidiasis (thrush) in HIV-infected patients.

About the study:

Patients are assigned by chance to receive one of three doses of BMS-207147 to take for five days. One of the three doses is real drug on Day 1 and placebo for four days. Neither patients nor their doctors will know which dose they are receiving until the study ends. On Days 1 and 5, patients will have 24-hour stays at the clinic for multiple blood draws. After the five-day treatment period, study visits will be on Days 9, 19 and 33. Blood samples and mouth cultures will be taken during study visits. The study lasts for 33 days.

Required:

- CD4 cell (T-cell) range: at least 50
- HIV positive
- At least 18 years old
- Uncomplicated OPC (thrush)

Not allowed:

- Women who are pregnant or breastfeeding
- Oral ulcers
- Esophageal candidiasis
- Use of any antifungal medicines, such as ketoconazole, fluconazole or itraconazole within seven days of study entry
- Use of any investigational drug within the past two months

Location:

UCSF AIDS Program at SFGH/ICTG
Dorie Heeren, RN
(415) 476-9296, ext. 305

60. Oropharyngeal Candidiasis Treatment: Fluconazole

Title:

ACTG 323/MSG 40: A Phase III Randomized Study of the Use of Fluconazole as Chronic Suppressive Therapy Versus Episodic Therapy in HIV Positive Subjects With Reccurent Oropharyngeal Candidiasis

Type of treatment:

Fluconazole: antifungal

Purpose:

To find out if it is better to take fluconazole three times a week to prevent thrush or esophageal candidiasis from coming back, or to wait until you get thrush or esophageal candidiasis again before taking it.

About the study:

Patients are assigned by chance to take fluconazole three times a week, or to take fluconazole only if they get thrush or esophageal candidiasis. There are no placebos in this study. Patients who join the study when they have thrush or esophageal candidiasis will be treated with fluconazole first, and then assigned by chance to take fluconazole every week, or to wait until they get thrush or esophageal candidiasis again. Study visits are every two months. Blood samples are drawn at each study visit. The study lasts two years.

Required:

- CD4 cell (T-cell) range: 150 or less
- HIV positive
- At least 13 years old
- At least one episode of oropharyngeal candidiasis (thrush) within the past six months

Not allowed:

- Three or more episodes of oropharyngeal candidiasis within the past three months
- Prior esophageal candidiasis
- Women who are pregnant or breastfeeding
- Any fungal infection requiring treatment with amphotericin-B, terbinafine, Lamisil or Ancoban
- Acute or active opportunistic infection requiring treatment

Location:

UCSD Treatment Center
Screening Nurse
(619) 543-8080

UCSF AIDS Program at SFGH/ACTU
David Rhodes, RN
(415) 476-9296 ext. 353

New

61. Oropharyngeal Candidiasis Treatment: Fluconazole

Title:

Fluconazole Suspension versus High Dose Fluconazole Tablets in Suppression of Fluconazole Refractory Thrush in HIV Patients

Type of treatment:

Fluconazole: antifungal

Purpose:

To compare fluconazole oral suspension to high-dose fluconazole tablets in patients who have not responded to treatment with the standard dose of fluconazole.

About the study:

Patients are assigned by chance to receive a liquid form of fluconazole or to receive fluconazole tablets. Fluconazole liquid is swished around the inside of the mouth and swallowed twice a day. Fluconazole tablets are taken by mouth once a day. Patients will take their assigned treatment for 14 days. Study visits are once a week for the first two weeks, then at Weeks 6, 10 and 14. The study lasts 14 weeks and **patients will be paid $100 for completing the study.**

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Diagnosis of OPC (oral thrush) which has not reponded to treatment with 14 days of 200 mg fluconazole

Not allowed:

- Esophageal candidiasis
- Use of other antifungal medications during the study

Location:

UCSF AIDS Program at SFGH/ICTG
Anna Smith, RN
(415) 476-9296, ext. 313

62. Oropharyngeal Candidiasis Treatment: SCH 56592, Fluconazole

Title:

C96-209: A Multicenter, Randomized, Double-Blind, Phase II Study to Evaluate the Safety, Tolerance and Efficacy of Multiple Doses of SCH 56592 Versus Fluconazole in the Treatment of Oropharyngeal Candidiasis (OPC) in HIV-Positive Patients

Type of treatment:

SCH 56592: antifungal
Fluconazole: antifungal

Purpose:

To see if the new drug SCH 56592 is safe and effective in treating oropharyngeal candidiasis (also called thrush). To see which dose of SCH 56592 is safest and most effective.

About the study:

Patients are assigned by chance to receive one of four doses of SCH 56592 or to receive fluconazole for 13 days. All patients will receive medication; there are no placebos in this study. Neither patients nor their doctors will know which medication or which dose they are taking until the study ends. Both medications are pills and taken by mouth. Study visits are once a week for the first two weeks, then every two weeks for two visits. Some sites may pay participants for completing the study.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 65 years old
- Symptomatic oral candidiasis

Not allowed:

- Active, acute infections other than OPC
- Use of rifampin, carbamazepine, phentoin, rifabutin, barbituates or isoniazid (INH) throughout the study
- Patients starting protease inhibitors for the first time in the 30 days prior to study entry
- Use of chemotherapy for cancer
- Use of systemic antifungals within 14 days of study entry
- Esophageal candidiasis
- Women who are pregnant or breastfeeding

Location:

East Bay AIDS Center
Jeremy Swartzberg
Weena Joshi
(510) 204-2782

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

New

63. Oropharyngeal Candidiasis Treatment: SCH 56592, Fluconazole

Title:

C97-331: Randomized Controlled Trial of SCH 56592 Oral Suspension Versus Fluconazole Suspension in the Treatment of Oropharyngeal Candidiasis (OPC) in HIV-Positive Patients

Type of treatment:

Fluconazole: antifungal
SCH 56592: antifungal

Purpose:

To compare two liquid medications for the treatment of oropharyngeal candidiasis (thrush).

About the study:

Patients are assigned by chance to receive either SCH 56592 oral suspension or fluconazole oral suspension for two weeks. Neither patients nor their doctors will know which medication they are using until the study ends. Both medications are liquids and taken into the mouth, swished and swallowed. Study visits are once a week for two weeks, then a one month follow-up visit. The study lasts 42 days.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Laboratory evidence of oral candidiasis (thrush)

Not allowed:

- Patients starting protease inhibitors for the first time within 30 days of study entry
- Use of rifampin, rifabutin, isoniazid, phenytoin, carbazepine or barbituates throughout the study
- Esophageal candidiasis
- Prior use of SCH 56592 within three months of study entry
- Patients whose thrush has not gotten better following treatment with fluconazole for at least two weeks, within three months of study entry
- Women who are pregnant or breastfeeding
- Use of Hismanal within 10 days of study entry
- Any systemic (such as Amphotericin B or 5-flucytosine) or oral antifungal therapy (such as mycelex, nystatin or oral amphotericin B) within one week prior to study entry

Location:

Kaiser San Francisco - HIV Research Unit
Anna Dowling, RN
(415) 202-3487 **OR**
Brian Goodroad, RN, MS
(415) 202-3480

64. CMV Retinitis Treatment: 1263W94

Title:

CMAA1004: A Phase I Trial to Evaluate the Ocular (Intravitreal) Penetration of 1263W94 After Multiple-Dose Oral Administration in AIDS Patients with CMV Retinitis

Type of treatment:

1263W94: antiviral

Purpose:

To see if oral 1263W94 crosses from the blood into the retina; to see how 1263W94 is processed by the body; to see if 1263W94 can reduce CMV viral load in blood and urine.

About the study:

Patients are assigned by chance to one of two doses of 1263W94; three times a day or twice a day. Patients will know which dosage they are taking. Patients will attend the clinic on Day 0 (the day prior to starting 1263W94), on Day 8 of the treament phase (the treament phase is eight days), and at two weeks after the last dose of 1263W94. On Day 8, patients will receive one dose of 1263W94 and stay in the clinic for 24 hours for multiple blood draws. Patients will also receive a ganciclovir implant on Day 8, at which time an eye tissue sample will be collected.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Males, 18 years of age or older
- Require ganciclovir implants, either initial placement or scheduled replacement for the treatment of CMV retinitis

Not allowed:

- Female patients
- Active hepatitis or cirrhosis
- Use of cidofovir for the treatment or prevention of CMV disease within three weeks of study entry
- Use of IV or oral ganciclovir, IV foscarnet or IV acyclovir for the treatment or prevention of CMV disease within one week of study entry
- Prior intraocular surgery (except for the placement of a ganciclovir implant) or cataract surgery
- Current diseases of the eye other than CMV
- Detached retina
- Patients who are lactose intolerant
- Gastrointestinal disorders which may interfere with oral dosing and drug absoprtion

Location:

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(949) 824-8303

65. CMV Retinitis Treatment: Cidofovir, Ganciclovir

Title:

ACTG 350/GCCRT: The Ganciclovir and Cidofovir CMV Retinitis Trial (GCCRT)

Type of treatment:

Ganciclovir, oral: antiviral
Ganciclovir, eye implants: antiviral
Cidofovir: antiviral

Purpose:

To compare the use of cidofovir to the use of ganciclovir implants plus oral ganciclovir with respect to the effectiveness in preventing vision loss in patients with CMV retinitis.

About the study:

Patients are assigned by chance to receive intravenous cidofovir or to receive ganciclovir intraocular implants and oral ganciclovir. Patients will know which treatment they are receiving. Patients assigned to receive cidofovir will have cidofovir given intravenously once a week for the first two weeks, then once every two weeks thereafter. Patients assigned to ganciclovir will have an intraocular device surgically implanted at baseline and every six to eight months thereafter in eyes with CMV retinitis. Oral ganciclovir is a pill and patients take four pills three times a day. Study visits are every four weeks. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Active CMV retinitis
- Visual acuity of 20/100 or better in at least one eye
- At least one lesion 750 microns or greater in size that can be photographed

Not allowed:

- Previous CMV treatment with cidofovir or the ganciclovir intraocular device
- Allergy to probenecid or sulfa sepsis syndrome
- Clinically significant cardiac disease, ischemia, congestive heart failure or arrhythmia
- Women who are pregnant or breastfeeding
- Current alcohol or substance abuse

Location:

LAC-USC Medical Center ACTU
Jennifer Lim, MD
(323) 342-6467

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(949) 824-8303

UCLA - Jules Stein Eye Institute
Michael Cornish, Ph.D.
(310) 794-5608

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

66. CMV Retinitis Treatment: GEM 132

Title:

132-100: An Open-Label, Phase I/II Study of the Safety and Efficacy of Single Escalating Doses of Intraocular GEM 132 in AIDS Patients with Relapsing Cytomegalovirus (CMV) Retinitis

Type of treatment:

GEM 132: antiviral

Purpose:

To see if injecting GEM 132 into the eye is safe and to see if it is effective in treating CMV retinitis.

About the study:

The first group of patients to enter this study will receive the lowest dose of GEM 132. If no bad side effects are seen, the next group of patients will receive a higher dose, and so forth until the highest dose researchers plan to study has been given. GEM 132 is given as a single injection into the eyeball. Study visits are once a week for the first month, then every two weeks for an additional two months. Eye exams and blood tests will be performed at study visits.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- CMV retinitis that has gotten worse

Not allowed:

- Prior use of ganciclovir implants or intravitreal cidofovir in the eye to be studied

Location:

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(949) 824-8303

67. CMV Retinitis Treatment: GEM 132

Title:

132-102: An Open-Label, Phase I/II Extension Study of the Safety and Efficacy of Multiple Doses of Intraocular GEM 132 in AIDS Patients with Relapsing Cytomegalovirus (CMV) Retinitis

Type of treatment:

GEM 132: antiviral

Purpose:

To provide re-treatment of GEM 132 for patients who experienced benefit from a previous intravitreal injection and to further study the safety of GEM 132..

About the study:

Patients who have completed at least eight weeks of the 12-week follow-up period for the GEM 132-100 study, and who appear to have benefited from treatment with GEM 132 will receive a repeat dose of GEM 132 at the same dose as they received in the GEM 132-100 study. Patients will be monitored for eight weeks. Patients who remain free of retinitis progression and have experienced no bad side effects after the first dose in this study can continue to receive up to four additional doses at the same dose level and at eight week intervals. There is a maximum of six injections; one from the GEM 132-100 study and five from this study.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Participation in GEM 132-100 and have completed at least eight weeks of the 12-week follow-up, and appeared to benefit from treatment with GEM 132, and experienced no bad side effects

Not allowed:

- Women who are pregnant or breastfeeding
- Prior use of ganciclovir eye implants within two months of study entry
- Intravitreal injection of cidofovir within four weeks of study entry
- Use of ISIS 2922 within four weeks of study entry
- The need to initiate local ocular CMV therapy prior to teatment with GEM 132
- Active alcohol and/or substance abuse

Location:

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(949) 824-8303

68. CMV Retinitis Treatment: ISIS 2922

Title:

ISIS 2922-CS2: A Randomized Comparison of Immediate versus Delayed Treatment with Intravitreal Injections of ISIS 2922 in Patients with Peripheral Cytomegalovirus (CMV) Retinitis

Type of treatment:

ISIS 2922: antisense

Purpose:

To find out if a new treatment for CMV retinitis, called ISIS 2922, is safe and effective.

About the study:

Patients are assigned by chance to receive either immediate or delayed treatment with ISIS 2922. Patients assigned to delayed treatment will receive ISIS 2922 if their CMV retinitis begins to spread. ISIS 2922 is given by injection into the eye. Injections are given once a week for three weeks, and then once every other week. At each visit, patients will have an eye exam and have blood tests performed. The study lasts 20 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Diagnosis of CMV retinitis in one eye, previously untreated
- At least 18 years old

Not allowed:

- Certain eye infections or other diseases of the eye
- Patients with retinal detachments
- Previous treatment for CMV retinitis
- Less than 10,000 platelets
- Women who are pregnant or breastfeeding

Location:

AIDS Community Research Consortium
Michele Downing, RN
(650) 364-6563

Community Eye Medical
Brian G. Terry, MD
Ramon Bautista
(626) 584-1200

69. CMV Retinitis Treatment: ISIS 2922

Title:

ISIS 2922-CS9: A Randomized Comparison of Two Dosage Schedules of Intravitreal ISIS 2922 for Patients with Advanced Cytomegalovirus Retinitis

Type of treatment:

ISIS 2922: antisense

Purpose:

To find a safe and effective dose of the new treatment called ISIS 2922 for advanced CMV retinitis.

About the study:

Patients are assigned by chance to receive ISIS 2922 either every other week, or every week for 3 weeks, then every other week until the end of the study. ISIS 2922 is given by injection into the eye. The study lasts 22 weeks. Study visits are every week for the first 3 weeks, then every other week until the end of the study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Diagnosis of advanced CMV retinitis in one or both eyes
- At least two previous anti-CMV retinitis therapies
- At least 18 years old

Not allowed:

- Previous ganciclovir implants
- Psuedoretinitis pigmentosa infection
- Syphilis, past or present
- Pregnant or nursing women

Location:

Community Eye Medical
Brian G. Terry, MD
Ramon Bautista
(626) 584-1200

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(949) 824-8303

UCSF AIDS Program at SFGH/ICTG
Nelson Murcar, RN
(415) 476-9296, ext. 333

70. CMV Retinitis Treatment: ISIS 2922

Title:

ISIS 2922-CS7: An Open-Label Study of the Safety and Efficacy of Intravitreal ISIS 2922 in Acquired Immune Deficiency Syndrome (AIDS) Patients With Cytomegalovirus Retinitis **(NOTE: Restricted to Patients Who Rollover From Another Controlled ISIS 2922 Trial or Have No other Therapeutic Alternatives Available to Them)**

Type of treatment:

ISIS 2922: antisense

Purpose:

To see if ISIS 2922 is safe and effective for treating CMV retinitis in patients who cannot take or were not helped by ganciclovir and/or foscarnet **or** have failed ISIS 2992 therapy on another controlled clinical trial.

About the study:

Patients in this study must rollover from another ISIS 2922 controlled trial. Patients will receive intravitreal injections (injections into the eyeball) of ISIS 2922 at one of two doses depending on the location and severity of their retinitis. There ia a three-week induction period followed by a maintenance period of at least 18 weeks. Induction is given on days 1, 8 and 15 and maintenance doses are given every 14 days, beginning on day 29. The study lasts at least 21 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- CMV retinitis in one or both eyes that was previously treated but is presently uncontrolled
- Not able to take, or unresponsive to other therapies
- Patients must rollover from another ISIS 2922 trial
- At least 18 years old

Not allowed:

- Women who are pregnant or breastfeeding
- Prior surgery to correct retinal detachment
- Past use of ganciclovir implants
- Past or current syphilis

Location:

AIDS Community Research Consortium
Michele Downing, RN
(650) 364-6563

Community Eye Medical
Brian G. Terry, MD
Ramon Bautista
(626) 584-1200

Retina-Vitreous Group - David Boyer, MD
Stone Blacka, CRC
(310) 854-6201

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(949) 824-8303

71. CMV Retinitis Treatment: ISIS 2922, Ganciclovir

Title:

ISIS 2922-CS3: A Randomized Comparison of Intravitreal ISIS 2922 plus Ganciclovir versus Ganciclovir as Treatment for Patients with Cytomegalovirus (CMV) Retinitis

Type of treatment:

ISIS 2922: antisense

Purpose:

To test the safety and effectiveness of a new drug called ISIS 2922 in combination with ganciclovir compared to ganciclovir alone for treatment of CMV retinitis.

About the study:

Patients are assigned by chance to receive ISIS 2922 plus ganciclovir or ganciclovir alone. ISIS 2922 is given by injection into the eye. Injections of ISIS 2922 are given every week for three weeks and then every other week until the end of the study. Ganciclovir is given by injection into a vein every 12 hours for 14 days. Patients who receive ganciclovir by injection can have a central line placed so they can receive injections at home. A central line is a small tube (catheter) semi-permanently inserted into a vein, often in the upper chest just below the collar bone. It will be removed at the end of the study. Patients taking ganciclovir will be referred to a home health agency so they can receive ganciclovir injections at home. After 14 days, patients will take ganciclovir tablets until the end of the study. At each visit, patients will have an eye exam and have blood tests performed. The study lasts 20 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- At least 18 years old
- Diagnosis of CMV which has not improved with other treatments

Not allowed:

- Certain eye infections or other diseases of the eye to be treated
- Patients with retinal detachments
- Prior treatment with ganciclovir implants or treatment with ganciclovir for more than 4 months
- Patients who have had CMV before
- Chronic diarrhea
- Less then 10,000 platelets
- Pregnant or breastfeeding women

Location:

AIDS Community Research Consortium
Michele Downing, RN
(650) 364-6563

Community Eye Medical
Brian G. Terry, MD
Ramon Bautista
(626) 584-1200

72. CMV Retinitis Treatment: Lobucavir, Oral Ganciclovir

Title:

AI459-030: A Pilot Placebo-Controlled Trial of Antiviral Activity of Oral Lobucavir versus Oral Ganciclovir in Individuals Receiving Intraocular Therapy for Cytomegalovirus (CMV) Retinitis

Type of treatment:

Ganciclovir, oral: antiviral
Lobucavir: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To observe the antiviral activity of lobucavir versus ganciclovir versus placebo given during treatment for CMV retinitis.

About the study:

Patients are assigned by chance to receive one of three doses of oral lobucavir or placebo or to receive oral ganciclovir to take in addition to continued intraocular treatments for CMV retinitis. Neither patients nor their doctors will know if they are taking lobucavir or placebo until after the antiviral activity portion of the study has ended (eight weeks). Patients assigned to take ganciclovir will know they are receiving ganciclovir. All medications are pills and taken by mouth. Study visits are every two weeks for the first eight weeks. After eight weeks, patients who have responded favorably to the six weeks of treatment may continue taking study medication after eight weeks with study visits occurring once a month. Patients who were assigned to lobucavir placebo will take open-label (real) lobucavir. The study will last indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Newly diagnosed first episode of CMV retinitis
- Intraocular therapy (implant or injections) within seven days prior to enrollment

Not allowed:

- Past IV anti-CMV therapy for more than four days for the current episode
- Treatment for previous CMV retinitis
- Diagnosis of CMV outside of the eye
- Any other active opportunistic infections requiring acute therapy
- Diarrhea that does not respond to treatment
- Women who are pregnant or breastfeeding

Location:

Community Eye Medical
Brian G. Terry, MD
Ramon Bautista
(626) 584-1200

73. CMV Retinitis Treatment: Valganciclovir

Title:

WV15705: An Open Label Study of the Safety and Tolerability of Valganciclovir, an Oral Prodrug of Ganciclovir, for the Treatment of Cytomegalovirus Retinitis in Subjects with AIDS

Type of treatment:

Valganciclovir: ganciclovir prodrug

Purpose:

To see if valganciclovir is safe and effective when used as a treatment for CMV retinitis.

About the study:

All patients will take valganciclovir. There are no placebos in this study. Vanciclovir is a pill and taken by mouth following a meal. Study visits are at baseline, two weeks, then once a month. Patients will be in this study indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- CMV retinitis
- At least four weeks of treatment with ganciclovir, foscarnet or cidofovir

Not allowed:

- Women who are pregnant or breastfeeding
- Severe, uncontrolled diarrhea
- Active CMV disease other than in the eyes

Location:

AIDS Community Research Consortium
Michele Downing, RN
(650) 364-6563

Institute for HIV Research & Treatment
CPMP - Davies Campus
Steve Collinson, RN
(415) 565-6660

Kaiser San Francisco Ophthalmology
Anna Dowling, RN
(415) 202-3981

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(949) 824-8303

74. CMV Retinitis Treatment: Valganciclovir, IV Ganciclovir

Title:

WV15376E: A Randomized, Controlled Comparison of the Safety and Efficacy of RS-79070 (Valganciclovir) vs IV Ganciclovir as Induction Therapy for the Treatment of Newly Diagnosed Cytomegalovirus Retinitis

Type of treatment:

Valganciclovir: ganciclovir prodrug

Purpose:

To see if the ganciclovir prodrug RS-79070, also called valganciclovir, is safe and effective when used as induction therapy in patients with newly diagnosed CMV retinitis. To see how RS-79070 affects the way ganciclovir is processed by the body and to see how RS-79070 affects CMV viral load.

About the study:

Patients with newly diagnosed CMV retinitis will be assigned by chance to receive either IV ganciclovir or valganciclovir for four weeks. IV ganciclovir is given by infusion into a vein. Valganciclovir is a pill and taken by mouth. Patients will know which treatment they are receiving. Patients assigned to receive IV ganciclovir will have a small tube (catheter) semi-permanently inserted into a vein in their upper chest to receive drug. After four weeks, all patients will be offered oral valganciclovir for longterm follow-up. Study visits are once a week for four weeks. The study lasts four weeks but patients may then enroll onto the longterm follow-up study which will have study visits every two weeks until progression of CMV retinitis.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Newly diagnosed with peripheral CMV retinitis

Not allowed:

- Women who are pregnant or breastfeeding
- Past CMV retinitis
- Severe uncontrolled diarrhea or evidence of malabsorption
- Prior use of any anti-CMV treatments such as ganciclovir, foscarnet, cidofovir or any investigational anti-CMV drugs for more than three weeks or within three months of study entry

Location:

AIDS Community Research Consortium
Michele Downing, RN
(650) 364-6563

Institute for HIV Research & Treatment
CPMP - Davies Campus
Steve Collinson, RN
(415) 565-6660

Kaiser San Francisco Ophthalmology
Anna Dowling, RN
(415) 202-3981

Pacific Oaks Research Group
Donna Morales, RN
(310) 360-8800

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

Retina-Vitreous Group - David Boyer, MD
Stone Blacka, CRC
(310) 854-6201

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(949) 824-8303

UCSD Treatment Center
Screening Nurse
(619) 543-8080

New

75. CMV Retinitis: Safety Study

Title:

ACTG 379: Discontinuation of Maintenance Therapy for Cytomegalovirus (CMV) Retinitis After Immune Reconstitution by Potent Antiretroviral Therapy: Safety, Virology and Immunology Profiles

Type of treatment:

Observational: none

Purpose:

To see if it is safe to discontinue CMV retinitis maintenance therapy for patients whose retinitis has healed and are taking HAART (Highly Active Antiretroviral Therapy)

About the study:

There are three groups of patients in this study. Patients in Groups 1 and 2 (see required below) will discontinue taking CMV retinitis maintenance treatment at the beginning of the study. Patients in Group 3 are those that **do not** wish to stop taking their CMV retinitis maintenance treatment. If patients' CMV reactivates or if their T-cell count falls below 50 cells/mm^3.

CMV medications may be restarted. After screening, study visits are every two weeks for the first two months, then once a month until the end of the study. Some study visits will include blood tests and eye exams (with photographs). Patients whose T-cell counts fall below 50 cells/mm^3 will have eye exams every two weeks. Patients whose CMV retinitis comes back will have their CMV medications restarted and be asked to return to the clinic for an additional eight months. The study lasts at least one year.

Required:

- CD4 cell (T-cell) range:
  Group 1: more than 100
  Group 2: between 50 amd 100 **AND** a 2 or more $\log_{10}$ reduction in viral load or undetectable viral load in response to HAART
  Group 3: at least 50
- Viral load range: Groups 1 and 3: not applicable
- HIV positive
- At least 13 years old
- Healed CMV retinitis after receiving treatment with any anti-CMV therapies for at least eight months prior to study entry; patients with ganciclovir implants must have had the implant for at least seven months prior to study entry
- At least eight weeks of HAART (any combination of at least two of the following: protease inhibitors, NRTIs, or NNRTIs)

Not allowed:

- Ganciclovir intraocular implants for less than seven months
- Any retinal lesions which would interfere with the ability to detect CMV retinitis reactivation or progression
- Any cancers requiring chemo or radiation therapy
- Evidence of any CMV disease outside of the eye which requires the use of anti-CMV medications

Location:

LAC-USC Medical Center ACTU
Gil Clemente, RN
(323) 343-8284

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

76. AIDS Dementia Complex Treatment: 1592U89

Title:

Kinetic Studies of Cerebrospinal Fluid (CSF) in Severe AIDS Dementia Complex Treated with a New Antiviral Drug, 1592U89

Type of treatment:

1592U89: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if 1592U89 is effective in reducing the amount of HIV virus in the central nervous system (spinal fluid) and in the blood. To see if 1592U89 helps treat AIDS dementia.

About the study:

All patients will take 1592U89 twice a day. 1592U89 is a pill and taken by mouth. Patients will have six lumbar punctures (spinal taps) during this study. A spinal tap is a needle passed into the spinal column between vertebra and having some fluid removed. Patients are paid $50 for the first spinal tap, $75 for the second, and $100 for the remaining four taps. Study visits are twice a week for the first two weeks, then at one month. Patients who did not have a visit at day 10 will have a visit at week 52. The study lasts one month, or for some, one year.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: more than 25,000 copies/mL
- CSF viral load range: more than 1,000 copies/mL
- HIV positive
- At least 18 years old
- Must have a diagnosis of AIDS Dementia Complex, Stage 3 or 4
- Must be on stable antiretroviral (no changes) therapy for at least six weeks prior to study entry

Not allowed:

- Any other neurological disease or complications, such as lymphoma, toxoplasmosis or meningitis
- Active or chronic infections that might interfere with the study

Location:

SFGH Department of Neurology
Richard W. Price, MD
(415) 206-3208

77. AIDS Dementia Complex Treatment: Memantine

Title:

ACTG 301: A Phase II, Randomized, Double-Blind, Placebo-Controlled Trial of Memantine for AIDS Dementia Complex (ADC) As Concurrent Treatment with Antiretroviral Therapy

Type of treatment:

Memantine: antiviral

Purpose:

To see if memantine has any effect on improving AIDS Dementia Complex. To see if memantine may have any effect on relieving painful peripheral neuropathy in patients being treated with antietroviral therapy.

About the study:

Patients will be assigned by chance to receive memantine or placebo to take with their current antiretroviral treatment(s). Neither patients nor their doctors will know which they are taking until the study ends. Memantine is a pill and taken by mouth. In addition to the screening process, there are eight study visits, once a month. The study lasts 16 weeks. After 16 weeks, all patients will be offered real memantine (no placebo) for an additional 12 weeks. There are two lumbar punctures (spinal taps) required; one at screening, the second at 16 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Diagnosis of AIDS Dementia Complex (ADC), stage 1, 2, or 3
- Must be on stable antiretroviral treatment for at least eight consecutive weeks prior to study entry **and** maintain this treatment throughout the study
- Impaired cognitive function as evidenced by neuropsychological tests

Not allowed:

- Any cancers other then basal cell, cervical or KS of the skin
- Any psychiatric diagnosis, such as schizophrenia or severe bipolar illness, which may affect the analysis of the study
- Active AIDS-defining opportunistic infections
- Neurologic disease unrelated to HIV, such as multiple sclerosis, stroke, degenerative disease
- Seizure disorder
- CNS infections or neoplasms, such as toxoplasmosis, CNS lymphoma, PML, cryptococcal meningitis, untreated syphilis
- Women who are pregnant or breastfeeding
- Active alcohol or drug abuse which may interfere with the study
- Use of IV Pentamidine or use of calcium channel antagonists (high blood pressure medications) within 30 days prior to study entry

Location:

Harbor-UCLA Medical Center
Mario Guerrero, MD
(310) 222-3848

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSD Treatment Center
Screening Nurse
(619) 543-8080

UCSF AIDS Clinic
David Gary, RN
(415) 476-9296, ext. 354

UCSF AIDS Program at SFGH/ACTU
David Rhodes, RN
(415) 476-9296 ext. 353

78. Diarrhea Evaluation and Treatment: Questran, ADEK

Title:

H7531-12449-01: A Study Evaluating Bile Acid Malabsorption and Small Bowel Overgrowth in HIV-Associated Diarrhea

Type of treatment:

Questran: cholesterol lowering agent
ADEK: vitamins

Purpose:

To see if HIV-related diarrhea is caused by bile acid malabsorption and/or an overgrowth of bacteria in the small bowel.

About the study:

Patients entering this study must have diarrhea that is not caused by any treatable organism. All patients who are having an endoscopy, which is a small tube inserted into the throat to examine the upper digestive tract, will have a sample of fluid removed from part of the intestine. Patients will also be asked to complete a breath test to determine if they have bile acid malabsorption. Finally, patients will be asked to complete a 24-hour fecal fat test. They will consume a 100 gram fat diet for three days and on the third day, they will collect all of their bowel movements in a container provided for this purpose. At the end of the 24-hour stool collection period, they will bring in the collected stool for analysis. After patients have been evaluated, a treatment plan will be implemented.

Required:

- CD4 cell (T-cell) range: not specified
- Viral load range: not specified
- At least 18 years old
- HIV positive
- HIV-associated diarrhea for which an endoscopic evaluation is considered necessary.
- Positive testing for fecal fat

Not allowed:

- Diarrhea caused by known treatable pathogens, such as parasites, amoebas
- Current active opportunistic infections requiring systemic treatment. Oral candidiasis (thrush) and KS are allowed.

Location:

Division of Gastroenterology at SFGH
Jamey Maimares, RD
(415) 206-4748

79. HIV-Related Upper Gastrointestinal Symptoms: Metoclopramide

Title:

Metoclopramide for Stasis Dyspepsia in Patients Infected with the Human Immunodeficiency Virus: A Randomized, Double-Blind, Placebo-Controlled Trial

Type of treatment:

Metoclopramide: antinausea/vomiting

Purpose:

To see if metoclopramide (also called Reglan) is safe and effective in relieving upper gastrointestinal symptoms.

About the study:

Patients are assigned by chance to receive metoclopramide or placebo. Both metoclopramide and its placebo are pills and patients will take one pill three times a day for four weeks. Neither patients nor their doctors will know which they are receiving until the study ends. Before taking any medication, patients will be required to fill out a questionnaire asking them about their symptoms and how they affect their lives. Patients will also receive a gastric emptying study as well as an abdominal ultrasound exam to determine the rate at which the stomach empties its contents. After patients have started taking treatment, another gastric emptying study and abdominal ultrasound wil be performed. Study visits are once a week and the study lasts one month.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Symptoms of stasis dyspepsia such as: nausea or vomiting; upper abdominal pain; early satiety; unexplained weight loss with anorexia
- Patients are scheduled for or have undergone a routine gastric emptying study

Not allowed:

- Symptoms due to other causes such as active peptic ulcer disease, untreated CMV enteritis, diabetes mellitus or gastric outlet obstruction
- Patients who have had all or part of their stomach surgically removed

Location:

Division of Gastroenterology at SFGH
Jamey Maimares, RD
(415) 206-4748

80. HIV and Hepatitis B Infection: OST 577

Title:

11-201: A Phase II Study to Evaluate the Preliminary Safety and Biological Activity of Human Anti-Hepatitis B Surface Antigen Monoclonal Antibody (OST 577) in Patients Infected With Both Human Immunodeficiency Virus-1 (HIV-1) and Hepatitis B Virus (HBV)

Type of treatment:

OST 577: monoclonal antibody

Purpose:

To see if OST 577, a monoclonal antibody for hepatitis B, is safe and if it has any biological activity against hepatitis B in patients who are infected with both HIV and hepatitis B.

About the study:

Patients are assigned by chance to one of two doses of OST 577 or placebo. Patients have a one in five chance of receiving placebo. Neither patients nor their doctors will know which they are receiving until the study ends. OST 577 is given by infusion into a vein. Infusions are given three times a week for two weeks, then every three weeks for a total of six months. There are a total of 14 infusions. **Patients will be paid $1,000 for completing this study.**

Required:

- CD4 cell (T-cell) range: at least 200
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Documented hepatitis B infection with serum ALT levels between 50 and 400 U/L on two occasions within two weeks of each other
- Must be taking at least 300 mg/day of 3TC for HIV infection for at least two weeks prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Detectable hepatitis B antibody
- Hepatitis C infection
- Active cancers
- Evidence of other known factors for liver damage, such as alcoholism, hepatitis A or E
- Active bacterial or systemic fungal infection
- Use of alpha interferon, interleukin-2 or HBIG within two months of study entry
- Use of any experimental treatment within one month of study entry

Location:

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

81. HIV and Hepatitis C Treatment: Alpha Interferon

Title:

IFN 9701: Evaluation of the Safety and Efficacy of Alferon N Injection in the Treatment of Subjects Co-Infected with HIV and Hepatitis C

Type of treatment:

Interferon, alpha: immune modulator

Purpose:

To see if Alferon N (interferon alpha-n3) is safe and effective in treating patients who are infected with chronic hepatitis C and co-infected with HIV.

About the study:

All patients will receive Alferon N injections. There are no placebos in this study. Alferon N is given by injection into a muscle three times a week. Patients who have not had a liver biopsy within 12 months of study entry will be required to undergo one prior to being screened for this study. Study visits are every two weeks for the first month, then once a month. The study lasts six months.

Required:

- CD4 cell (T-cell) range: at least 200
- HIV viral load range: not applicable
- Hepatitis C viral load range: at least 2,000 copies/mL
- Between 18 and 60 years old
- HIV positive
- Biopsy-proven hepatitis C

Not allowed:

- Prior hepatitis B
- Prior occurence of liver failure
- Prior use of alpha interferon

Location:

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

Tower Infectious Diseases
Tim Jordan, RN
(310) 358-2300 ext. 114

82. HIV and Hepatitis C Infection: Observational

Title:

ACTG 383: Dynamics of Hepatitis C Infection in Subjects with Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) Receiving Highly Active Antiretroviral Therapy (HAART)

Type of treatment:

Observational: none

Purpose:

To learn more about hepatitis C virus (HCV) in patients who are taking highly active antiretroviral therapy (HAART). To see if patients co-infected with hepatitis C have more frequent liver function test abnormalities while receiving HAART.

About the study:

Patients enrolled in this study **must also be co-enrolled in another ACTG-sponsored research study which uses highly active aniretroviral therapy** to treat HIV. No study treatments are given as part of this study. This study only involves the evaluation of blood tests for hepatitis C virus. Blood draws are at weeks 2, 4, 8, 16, 24, 32, 40 and 48. The study lasts 48 weeks.

Required:

- Viral load range: at least 2,500 copies/mL
- At least 13 years old
- Have tested positive for hepatitis C virus
- Must be co-enrolled in another ACTG primary trial using HAART within 72 hours of entry into this study

Not allowed:

- More than two weeks use of any protease inhibitors
- Prior use of hydroxyurea, DMP 266, 1592U89, adefovir dipivoxil
- Liver disease, manifested by ascites, bleeding varices, coagulation disorders
- Active hepatitis B infection
- Use of interferon for any reason within three months of study entry
- Active alcohol and/or substance abuse
- Use of immunomodulators, such as interleukins, DNCB, thalidomide, thymopentin within four weeks of study entry
- Any cancers requiring systemic chemotherapy

Location:

Stanford University Medical Center
Jane Norris, PA-C
(650) 723-2805

UCSD Treatment Center
Screening Nurse
(619) 543-8080

83. Herpes Simplex: Observational

Title:

Multisite Antiviral Resistance Studies: Pilot Surveillance for Acyclovir-Resistant HSVII

Type of treatment:

Observational: none

Purpose:

To determine the extent of acyclovir-resistant herpes simplex. To collect and store specimens of acyclovir-resistant genital herpes simplex for in-depth lab studies.

About the study:

Patients joining this study will have one study visit where a herpes swab will be taken and patients will fill out a questionnaire. This study is limited to patients who have peri-anal or rectal herpes.

Required:

- Herpes simplex lesion in the peri-anal or rectal area

Not allowed:

- No exclusions

Location:

San Francisco VA Medical Center
Sandy Charles, RN
(415) 221-4810, ext. 3763

84. KS Treatment: Alpha Interferon, Protease Inhibitor Therapy

Title:

AMC004: Protease Inhibitor-Containing Therapies Combined with Interferon alpha-2b in Patients with AIDS-Related Kaposi's Sarcoma

Type of treatment:

Interferon, alpha: immune modulator

Purpose:

To see if interferon alpha-2b is safe and well tolerated when combined with protease inhibitors. To see what effect this combination has on tumor response, CD4 and CD8 cells, and to see how these drugs interact and are processed by the body.

About the study:

Patients are assigned by chance to receive a protease inhibitor-based antiretroviral treatment plus alpha interferon or to receive a protease inhibitor-based treatment alone. Patients will know which medications they are taking. Those patients assigned to receive alpha interferon will receive the lowest dose, then increasing doses if alpha interferon is well tolerated. Alpha interferon is given by injection under the skin and patients will be taught how to give themselves injections at home if they wish. Injections are given once a day. Study visits are every two weeks for the first eight weeks, then once a month. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Biopsy-confirmed cutaneous KS with at least three lesions
- All other antiretroviral therapy, other than d4T, must be discontinued for at least 14 days before study entry

Not allowed:

- Current acute opportunistic infections
- KS that has spread to the internal organs
- Any other cancers other than basal cell carcinoma or ano-genital neoplasia
- Acute or chronic pancreatitis within two years of study entry
- Severe peripheral neuropathy within four months of study entry
- Prior use of systemic alpha interferon, ritonavir or indinavir
- Use of chemotherapy, radiation, corticosteroids, rifampin or rifabutin within 14 days of study entry

Location:

AIDS Oncology Practice at
UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

LAC-USC Medical Center
Suzanne Cabriales, RN
(323) 343-8270

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF AIDS Program at SFGH/ICTG
Matt Kinder
(415) 476-9296 ext. 316

85. KS Treatment: Radiation

Title:

UCD95KS001: A Prospective, Randomized Controlled Trial of Radiation Therapy for Early Stage AIDS-Associated Kaposi's Sarcoma

Type of treatment:

Radiation: cancer treatment

Purpose:

To see which dose of radiation is best for treating localized KS lesions.

About the study:

Patients entering this study must have at least two KS lesions that could benefit from therapy. Two lesions will be treated with different doses of radiation. One lesion will receive a lower dose once. The other lesion will receive a higher dose every day for ten days. Patients will come to the clinic everyday for two weeks during radiation treatment. Follow-up visits are at one month, then every two months until progression of the treated lesions. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- At least two, biopsy-proven KS lesions of the skin

Not allowed:

- Any other cancers in the past five years, except non-melanoma skin cancer
- KS of the internal organs

Location:

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

86. KS Treatment: SU5416

Title:

5416.003: A Multicenter, Dose-Escalating Study in Patients With Cutaneous AIDS-Related Kaposi's Sarcoma

Type of treatment:

SU5416: antitumor

Purpose:

To see if SU5416 is safe, well-tolerated and effective in treating Kaposi's sarcoma of the skin.

About the study:

This is a dose-escalating study. This means that the first patients to enroll in the study will receive the lowest dose of SU5416. If no bad side effects are seen, the next group of patients will receive a higher dose, and so forth until the highest dose researchers plan to study has been given or the highest dose that does not cause bad side effects has been found. SU5416 is given by infusion into a vein twice a week for four weeks (one cycle). Patients who have not experienced bad side effects and who seem to be responding to the medication will be permitted to continue receiving SU5416 in four-week cycles up to one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Biopsy-proven KS of the skin
- At least five skin lesions, each of which is at least 10mm long or has been present for at least 30 days and has not been treated with laser therapy or has not been biopsied
- Patients who are taking antiretroviral medicines must be stable (no changes) for at least six weeks prior to study entry and remain on the same therapy throughout this study

Not allowed:

- Women who are pregnant or breastfeeding
- Current uncontrolled serious infections
- Other cancers except basal cell carcinoma of the skin and cervical cancer
- Use of any KS therapy within three weeks of study entry
- Use of erythropoeitin, G-CSF or GM-CSF within two weeks of study entry
- Any surgery within four weeks of study entry

Location:

HIVCare, Saint Francis Memorial Hospital
Mark Bowers
(415) 353-6215

LAC-USC Medical Center
Suzanne Cabriales, RN
(323) 343-8270

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

87. KS Treatment: Topotecan

Title:

SKF 104864-4: An Open, Non-Comparative, Phase II Study of Topotecan, Given as a 30-Minute Infusion on Five Consecutive Days Every 21 Days, to Patients with Kaposi's Sarcoma

Type of treatment:

Topotecan: cellular inhibitor

Purpose:

To learn whether and how quickly AIDS-related KS gets better with treatment with Topotecan.

About the study:

All patients receive treatment with Topotecan. Topotecan is given as an infusion into a vein, and participants will need to have a "PIC line" inserted. A PIC line is a small tube (catheter) semi-permanently inserted into a vein in the arm. Treatments are given through this tube at home for 30 minutes on five consecutive days every 21 days. All participants go through at least two 21-day cycles, given 4 weeks apart. Patients must come to the clinic weekly to get more drug to infuse at home.

Required:

- CD4 cell (T-cell) range: above 50
- HIV positive
- At least 18 years old
- KS that got worse after treatment with at least 2 different kinds of chemotherapy
- At least 3 to 5 KS lesions that can be measured

Not allowed:

- More than 2 prior chemotherapy regimens
- KS that has spread to the lungs
- Extensive radiation within last 2 weeks

- Serious opportunistic infection requiring acute therapy (long term MAC treatment is allowed)
- Pregnant or breastfeeding women

Location:

AIDS Oncology Practice at
UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

88. KS: Observational

Title:

BRL-002: The Establishment of Kaposi's Cell Lines From Volunteer Patient Punch Biopsy Specimens

Type of treatment:

Observational: none

Purpose:

To collect KS lesion cells to be grown in the laboratory and used to measure response to radiation and other possible treatments.

About the study:

Patients will have some tissue removed from one of their KS lesions. The site will be cleaned and numbed and a small piece of KS lesion will be removed by a small incision. Patients will receive a single stitch and dressing and be asked to return in one week to have the stitch removed and the site inspected for any sign of infection. **Patients will receive a check for $25 within one month of the procedure for participating in this project.** Patients will be required to give their name, address and Social Security number.

Required:

- KS of the skin

Not allowed:

- No exclusions

Location:

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

89. Epstein Barr-Associated Malignancies Treatment: 5-Azacytidine

Title:

AMC001/T93-0116: A Pilot Study of 5-Azacytidine Given as a 7-Day Continuous Infusion in HIV Patients with Relapsed and/or Refractory EBV-Associated Malignancies

Type of treatment:

5-Azacytidine:

Purpose:

To see if 5-azacytidine is a safe and effective treatment for patients with Epstein Barr-associated malignancies that have not gotten better with standard chemotherapy treatment.

About the study:

Patients will enter the hospital and receive 5-azacytidine for seven consecutive days. 5-azacytidine is given by infusion into a vein. All patients will receive 5-azacytidine. There are no placebos. Patients will receive one to three courses of treatment (infusion over one week every 28 days) depending on how well the treatment is tolerated and on how the tumor responds to treatment. The study lasts at least two months.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- At least 18 years old
- HIV positive
- Diagnosis of Hodgkin's or non-Hodgkin's lymphoma with Epstein Barr virus involvement

Not allowed:

- CNS cancers
- Women who are pregnant or breastfeeding
- Active, uncontrolled infections

Location:

AIDS Oncology Practice at
UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

LAC-USC Medical Center
Norris Cancer Hospital
Maria Palmer, PA-C
(323) 865-0371

UCSF AIDS Program at SFGH/ICTG
Matt Kinder
(415) 476-9296 ext. 316

90. Lymphoma, AIDS-Associated Treatment: 90Y-Lym-1

Title:

UCD-RT0301: Immunotherapy of AIDS-Associated Lymphoma With 90Y-Lym-1

Type of treatment:

90Y-Lym-1: radiation therapy

Purpose:

To see if 90Y-Lym-1 is a safe and effective treatment for AIDS-associated lymphoma.

About the study:

All patients in this study will receive 90Y-Lym-1. 90Y-Lym-1 is given by infusion into a vein. Infusions are given every four weeks for 12 weeks. Patients will be in this study until their lymphoma progresses.

Required:

- CD4 cell (T-cell) range: at least 25
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Diagnosed with AIDS-associated lymphoma

Not allowed:

- Any other cancers within the last five years, except non-melanoma skin cancer and KS of the skin
- Women who are pregnant or breastfeeding

Location:

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

91. Non-Hodgkin's Lymphoma Treatment: CHOP, d4T, 3TC, Indinavir

Title:

AMC005: Pilot Study of the Effects of Combination Chemotherapy (modified CHOP) and Triple Antiretroviral Therapy on Outcome and Viral Load in the Treatment of AIDS-Related Non-Hodgkin's Lymphoma

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Chemotherapy, systemic: chemotherapy
Indinavir: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if modified CHOP chemotherapy combined with triple antiretroviral therapy is effective in treating AIDS-related non-Hodgkin's lymphoma and in fighting HIV disease.

About the study:

All patients will receive CHOP chemotherapy. CHOP chemotherapy is cyclophosphamide, doxorubicin, vincristine and prednisone. Chemotherapy is given by infusion into a vein every three weeks (one cycle). Patients will receive a minimum of four cycles or two cycles beyond complete response. No more than six cycles will be given. At the start of the second cycle, patients will take 3TC, d4T and indinavir. Viral load tests will be done at the beginning and middle of the first and second cycles of chemotherapy; then monthly for three months; then every three months. The study lasts one year

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 70 years old
- Biopsy-proven B-cell lymphoma

Not allowed:

- Patients with CNS lymphoma
- Current opportunistic infection, other than MAC, requiring antibiotic treatment
- Other cancers except cervical and basal cell
- Use of immunomodulators, such as interleukins or interferons, within two weeks of study entry
- Prior use of any protease inhibitors
- Women who are pregnant or breastfeeding

Location:

AIDS Oncology Practice at
UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

LAC-USC Medical Center
Norris Cancer Hospital
Maria Palmer, PA-C
(323) 865-0371

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSD AIDS Malignancy Program
Wayne Saville, MD
(619) 543-2214

UCSF AIDS Program at SFGH/ICTG
Matt Kinder
(415) 476-9296 ext. 316

92. Non-Hodgkin's Lymphoma Treatment: DaunoXome

Title:

DaunoXome In the Treatment of HIV-Associated Refractory or Relapsed Non-Hodgkin's Lymphoma (Phase II)

Type of treatment:

DaunoXome: chemotherapy

Purpose:

To see if DaunoXome is safe and effective in treating non-Hodgkin's lymphoma in patients that have tried at least one other treatment with no response and/or for patients who have relapsed after treatment.

About the study:

All patients enrolling in this study will have tried at least one other potential treatment or have relapsed after using that treatment. All patients will receive DaunoXome. DaunoXome is given by infusion into a vein. Medication is given every three weeks. This study will last indefinitely. Patients are required to have a bone marrow biopsy for this study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Confirmed diagnosis of intermediate or high grade non-Hodgkin's lymphoma
- Patients must have received at least one potential treatment for non-Hodgkin's lymphoma

Not allowed:

- Any chemotherapy, radiation or hormone therapy must have been discontinued for at least two weeks prior to enrollment
- Patients with CNS lymphoma
- Women who are pregnant or breastfeeding
- Any active AIDS-defining opportunistic infection within two weeks prior to enrollment, except herpes simplex or oropharyngeal candidiasis (thrush)
- Cardiac conditions such as atrial arrhythmias, unstable angina, or myocardial infarction, congestive heart failure, coronary artery bypass or coronary angiopasty
- Any cancers other than skin, cervical, or KS of the skin

Location:

LAC-USC Medical Center
Norris Cancer Hospital
Byron Espina
(323) 865-0371

93. Non-Hodgkin's Lymphoma Treatment: Diethylhomospermine

Title:

Diethylhomospermine (DEHSPM) in HIV-Associated Non-Hodgkin's Lymphoma: A Phase I/II Study

Type of treatment:

DEHSPM: chemotherapy

Purpose:

To see which dose of DEHSPM is best tolerated and to measure the response rate of non-Hodgkin's lymphoma.

About the study:

This is a dose-escalating study. That means that the first patients to enter the study will receive the lowest dose of DEHSPM. If no bad side effects are observed, the next group of patients will receive a higher dose, and so forth until the highest dose has been given that researchers plan to study or the highest dose is found that does not cause bad side effects. DEHSPM is given by injection under the skin every day for six days (one cycle) and the cycle is repeated every three weeks. Study visits are once a week and the study lasts until patients' disease gets worse.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Diagnosis of non-Hodgkin's lymphoma

Not allowed:

- Active opportunistic infections except herpes simplex or oral thrush (candida)

Location:

AIDS Oncology Practice at
UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

UCSF AIDS Program at SFGH/ICTG
Gail Hodgins
(415) 476-9296 ext. 301

94. Non-Hodgkin's Lymphoma Treatment: Interleukin-2

Title:

AMC003: Low-Dose Interleukin-2 in AIDS-Lymphoma: A CALGB Study

Type of treatment:

Interleukin-2: immune modulator

Purpose:

To see what effect interleukin-2 (IL-2) has on tumor response and survival and to see if it has any activity against HIV infection.

About the study:

Interleukin-2 is given by injection under the skin. Patients will be taught how to give themselves injections at home. Injections will be given every day for one year. Patients will need to come to the clinic every two weeks to pick up a supply of syringes already filled with interleukin-2. Study visits are at Weeks 6, 10, 12, then every 12 weeks for one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 16 years old
- Diagnosis of non-Hodgkin's lymphoma that is in partial remission after completing standard therapy

Not allowed:

- Women who are pregnant or breastfeeding
- Current opportunistic infections
- Any other cancers other than basal cell carcinoma of the skin
- CNS lymphoma
- Previous treatment with interleukin-2

Location:

AIDS Oncology Practice at
UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

LAC-USC Medical Center
Norris Cancer Hospital
Byron Espina
(323) 865-0371

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSD AIDS Malignancy Program
Wayne Saville, MD
(619) 543-2214

UCSF AIDS Program at SFGH/ICTG
Matt Kinder
(415) 476-9296 ext. 316

95. Non-Hodgkin's Lymphoma Treatment: PEG L-Asparaginase

Title:

17NHL-96-3: A Phase I Study of PEG L-asparaginase in the Treatment of Refractory/Relapsed AIDS-Related Non-Hodgkin's Lymphoma (AIDS-NHL)

Type of treatment:

L-Asparaginase:

Purpose:

To see if PEG L-Asparaginase is safe and to determine the maximum dose that is tolerated in patients who have relapsed NHL or are not responding to other treatment. To see how PEG L-asparaginase is processed by the body. To see what level of anti-tumor response PEG L-asparaginase has.

About the study:

This is a dose-ranging or dose-escalating study. This means that the first patients to enroll on the study will receive the lowest dose of PEG L-asparaginase. If this dose is found to be well-tolerated, the next group of patients will receive a higher dose. This procedure is followed until the highest dose of PEG L-asparaginase that researchers plan to study has been given **or** the highest dose is found which does not cause bad side effects. PEG L-asparaginase is given by injection into a muscle. Patients will receive injections every two weeks until they develop intolerable side effects **or** they have complete remission (disappearance of lymphoma) **or** they choose to stop the treatment. Study visits are every two weeks and the study lasts at least one month. Patients will be required to have a lumbar puncture (spinal tap), CT scan of the head and bone marrow biopsy at the beginning of the study.

Required:

- CD4 cell (T-cell) range: not applcable
- Viral load range: not applicable
- HIV positive
- At least 17 years old
- Diagnosis of non-Hodgkin's lymphoma that has come back **OR** never gone away with prior exposure to any chemotherapy or radiation treatment

Not allowed:

- Acute intercurrent infection
- Patients with other cancers except basal cell carcinoma, cervical cancer, or KS of the skin, not requiring systemic chemotherapy
- CNS lymphoma
- Past or current pancreatitis
- Treatment with chemotherapy or radiation therapy within two weeks of study entry
- Prior use of L-asparaginase
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center
Norris Cancer Hospital
Laura Harvey-Buchanan, RN
(323) 226-4578

96. Non-Hodgkin's Lymphoma and HIV Treatment: Chemotherapy, Ribozyme Gene Therapy

Title:

17NHLK-97-2: High Dose Chemotherapy and Autologous Peripheral Stem Cell Transplantation for HIV Lymphomas: A Phase IIa Study of Comparative Marking Using a Ribozyme Gene and a Neutral Gene

Type of treatment:

Chemotherapy, systemic: chemotherapy
Anti-HIV Ribozyme: gene therapy

Purpose:

To see if genetically-engineered cells that are resistant to HIV can be safely given to lymphoma patients currently undergoing high-dose chemotherapy. To see if these altered cells can mature and circulate in the bloodstream. The therapeutic gene used in this study is called a ribozyme.

About the study:

Patients who are undergoing chemotherapy for non-Hodgkin's lymphoma will take their chemotherapy along with G-CSF for eight days to mobilize the stem cells (undeveloped blood cells). After eight days, patients will give blood samples by a process called apheresis, by which stem cells are removed. The remaining blood cells and plasma are returned to the patient. The stem cells are taken to the laboratory and the patient's CD34+ cells are separated from the stem cells. Half the patient's CD34+ cells will receive the gene containing the anti-HIV ribozyme and half the cells will receive a neutral gene. The CD34+ cells are then returned to the patient by infusion into a vein. Study visits are every three months for the first year, then every six months for the second year. Patients will then be seen once a year for an indefinite period of time.

Required:

- CD4 cell (T-cell) range: at least 100 at the time of lymphoma diagnosis
- Viral load range: less than 10,000 copies/mL
- HIV positive
- Between 18 and 60 years old
- Must be on at least two antiretrovirals. AZT may not be used because of its bone marrow toxicity
- Biopsy-proven non-Hodgkin's lymphoma, intermediate or high grade
- Demonstrated complete or partial remission with chemotherapy

Not allowed:

- Women who are pregnant or breastfeeding
- Any prior cancers other than basal cell carcinoma of the skin
- Evidence of active CNS lymphoma
- Prior CMV disease, such as retinitis or gastritis
- Bacterial or fungal infections requiring antibiotics within 14 days of study entry
- Any opportunistic infections within the past year (such as PCP, toxoplasmosis, MAC, or cryptosporidiosis) or evidence of dementia or encephalopathy
- Active hepatitis B and/or antibody positive for hepatitis C

Location:

City of Hope National Medical Center
John Zaia, MD
(626) 301-8434

LAC-USC Medical Center
Norris Cancer Hospital
Byron Espina
(323) 865-0371

New

97. MAC Prevention: Observational

Title:

ACTG 393: A Study of Discontinuing Maintenance Therapy in Subjects with Disseminated *Mycobacterium avuim* Complex (DMAC)

Type of treatment:

Observational: none

Purpose:

To see if MAC prevention medications can be stopped in patients who have had MAC before, been treated for at least 12 months, are now free of any signs of MAC for at least 16 weeks, and have a CD4 cell (T-cell) count of 100 or more.

About the study:

Patients enrolling in this study will be required to have a bone marrow biopsy. A bone marrow biopsy is performed by inserting a needle into the hip bone and removing a small piece of bone marrow. Patients will continue to take their MAC prevention medicines for the first six weeks of the study. After six weeks, patients will stop their MAC medications if their MAC blood tests are negative and they show no signs of MAC disease. Patients must continue to take their antiretroviral medications throughout the study. Study visits are at Weeks 6, 10 and 14, then every two months until the end of the study. The study lasts about 27 months.

Required:

- CD4 cell (T-cell) range: at least 100
- HIV positive
- At least 13 years old
- Use of antiretroviral therapy for at least 16 weeks and have made no changes to that therapy for at least eight weeks prior to study entry
- Previous diagnosis of MAC
- Must be on a minimum of two drug anti-MAC therapy for at least 12 months consisting of either clarithromycin or azithromycin plus either ethambutol or rifabutin

Not allowed:

- Signs of MAC disease, such as fever, night sweats, weight loss, diarrhea or liver and/or spleen changes within 16 weeks of study entry
- Use of immunomodulators (interleukins, interferons), corticosteroids, chemotherapy, vaccines, IVIG, or GM-CSF within two months of study entry
- Women who are pregnant or breastfeeding
- Patients requiring the use of azithromycin, clarithromycin, ethambutol or rifampin for the treatment of diseases other than MAC

Location:

LAC-USC Medical Center ACTU
Frances Canchola, RN
(323) 343-8281

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

98. MAC Prevention: Azithromycin

Title:

ACTG 362: A Randomized, Placebo-Controlled Trial to Determine the Efficacy of Azithromycin Prophylaxis for the Prevention of *Mycobacterium avium* Complex (MAC) and Other Infections in Subjects Who Have Achieved an Increase in CD4 Cells on Antiretroviral Therapy

Type of treatment:

Azithromycin: antibacterial

Purpose:

To compare the time to the development of MAC disease in patients taking azithromycin to those who are taking placebo in patients who have had an increase in their CD4 (T-cell) counts from below 50 cells/mm^3 to above 100 cells/mm^3.

About the study:

Patients are assigned by chance to receive azithromycin or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. Both azithromycin and its placebo are pills and taken by mouth once a week. Patients who develop a drop in CD4 (T-cells) count below 50 on two separate occasions will be offered open-label (real) azithromycin. Study visits are every eight weeks. The study lasts at least 72 weeks.

Required:

- CD4 cell (T-cell) range: two counts of less than 50 on two separate occasions **OR** one count of less than 50 in the past and not known to be above 150 within three months prior to the count of less than 50 **AND** a treatment-induced increase of CD4 count to above 100 on two separate occasions
- HIV positive
- At least 13 years old
- Must be receiving antiretroviral therapy
- Patients receiving MAC prophylaxis at entry may be enrolled but must discontinue at study entry

Not allowed:

- Past or current use of interleukin-2
- Prior positive MAC culture from blood or other body site
- Known or suspected tuberculosis infection requiring therapy other than INH prophylaxis
- Concurrent treatment with azithromycin, clarithromycin, erythromycin, ethambutol, rifampin or rifabutin during the study

Location:

Harbor-UCLA Medical Center
Sandra Houston, LVN
(310) 222-5291

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

UCSD Treatment Center
Screening Nurse
(619) 543-8080

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

UCSF AIDS Program at SFGH/ACTU
David Rhodes, RN
(415) 476-9296 ext. 353

99. MAC and Bacterial Pneumonia Prevention: Azithromycin

Title:

CPCRA 048: A Randomized, Double-Blind, Placebo-Controlled Trial of Prophylaxis for Disseminated *Mycobacterium avium* Complex Disease and Bacterial Pneumonia Versus Deferred Prophylaxis in HIV-Infected Patients Who Experience Rebound in CD4+ Cell Count Due to Active Antiretroviral Therapy

Type of treatment:

Azithromycin: antibacterial

Purpose:

To see if patients who have experienced a significant recovery of their CD4 cell (T-cell) counts following antiretroviral therapy, should take azithromycin to help prevent *Mycobacterium avium* Complex (MAC) and bacterial pneumonia.

About the study:

Patients are assigned by chance to receive azithromycin or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. Azithromycin and its placebo are tablets and taken once a week. Study visits are once every four months. If patients CD4 cell counts return to less than 50 (on two occasions), they will be switched to real (open-label) azithromycin. The study lasts at least 18 months.

Required:

- CD4 cell (T-cell) range: at least two counts of more than 100 obtained at least 30 days apart
- A CD4 cell count of less than 50 anytime in the past
- HIV positive
- At least 13 years old

- Patients must have started or changed antiretroviral treatment during the period between the CD4 cell count of less than 50 and the first CD4 cell count of more than 100
- Patients must be taking at least one antiretroviral medication at the time of study entry
- Must be willing and able to discontinue taking nonstudy MAC prevention medications

Not allowed:

- Any past serious adverse experience using azithromycin
- Past or current MAC or current signs or symptoms suggestive of MAC disease
- Any illness requiring the continued use of medications having activity against MAC, such as rifampin, rifabutin, ethambutol, clarithromycin
- Use of interleukin-2 within six months of study entry

Location:

Community Consortium
Available at the locations listed on page 115
(415) 476-9554

100. Macrolide Resistance: Azithromycin, Clarithromycin

Title:

The Development of Macrolide Resistance to Respiratory Flora in Patients Receiving Either Clarithromycin or Azithromycin for *Mycobacterium avuim* Complex Prophylaxis

Type of treatment:

Azithromycin: antibacterial
Clarithromycin: antibacterial

Purpose:

Azithromycin and clarithromycin are are antibiotics and in a class of drugs called macrolides. The purpose of this study is to see if the normal bacteria in the nose, mouth and throat of patients being treated with azithromycin is more likely to become resistant to macrolides than that of patients being treated with clarithromycin.

About the study:

During screening, patients will have a physical exam, blood tests and a Q-tip will be used to collect samples of secretions from the nose and throat. Eligible patients are assigned by chance to receive clarithromycin twice a day or azithromycin once a week for 12 weeks. Study visits are at six weeks and 12 weeks and will include blood tests and nose and throat samples. The study lasts 12 weeks and **patients will be paid $150 for completing the study.** Azithromycin and clarithromycin will not be available for patients when the study is completed.

Required:

- CD4 cell (T-cell) range: 200 or less
- HIV positive
- At least 18 years old
- If on antiretroviral medications, must be on stable (no changes) doses for at least 30 days prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Use of immunomodulators (such as interferons, interleukins or steroids), chemotherapy, vaccines, IVIG or G-CSF within two months of study entry
- Use of azithromycin or clarithromycin within six months of study entry
- Active opportunistic infections

Location:

UCSF AIDS Program at SFGH/ICTG
Dorie Heeren, RN
(415) 476-9296, ext. 305

101. PCP Prophylaxis: Atovaquone

Title:

A Randomized, Open-Label, Multicenter Cross-Over Study to Observe Subjects' Preference for Two Packaged Forms of Mepron Suspension

Type of treatment:

Atovaquone: antibacterial

Purpose:

To see if patients prefer Mepron (atovaquone) in a multiple-dose bottle or in individual-dose sachets for PCP prophylaxis.

About the study:

Patients are assigned by chance to receive Mepron from a bottle or to receive individual-dose sachets (packets). Both forms are liquids and swallowed. Patients assigned to Mepron from the bottle will take two teaspoons full every day and those assigned to sachets will drink two packets a day. After 21 days, patients will return to the clinic and receive the alternate form of Mepron and take that form for an additional 21 days. Patients will then return to the clinic to evaluate their preference and satisfaction. The study lasts six weeks.

Required:

- CD4 cell (T-cell) range: 200 or less **OR** a prior episode of PCP regardless of CD4 cell count
- HIV positive
- At least 18 years old

Not allowed:

- Active PCP
- Current use of Mepron for PCP prophylaxis
- Current upper respiratory infections
- Active tuberculosis
- Current use of rifampin
- Women who are pregnant or breastfeeding

Location:

Sherman Oaks Hospital Research Institute
Monica Medina
(818) 205-1902

New

102. PCP Prophylaxis: Observational

Title:

ACTG 888: Impact of Discontinuing PCP Prophylaxis in Subjects Receiving Antiretroviral Therapies Who Have Had Increases in CD4 Counts to More Than 200 Cells/mm^3

Type of treatment:

Observational: none

Purpose:

To see how often PCP occurs in patients who stop taking medicines to prevent PCP because their CD4 cells (T-cells) have risen to above 200 cells/mm^3.

About the study:

Patients who enter this study will stop taking medications to prevent PCP. Study visits are once a month for the first two months, then every two months until the end of the study. Patients who develop PCP will restart medicine for the treatment of PCP and be contacted every eight weeks. Patients whose T-cells fall beow 200 cells/mm^3 will have their T-cell count rechecked in four weeks and, if still below 200, will restart medicines to prevent PCP and continue with the study. The study lasts about 2 and a half years.

Required:

- CD4 cell (T-cell) range: must have had a count of 100 or less with no history of PCP **OR** a prior episode of PCP within six months of study entry **AND** a count of 200 cells or more on two occasions at least 12 weeks apart
- HIV positive
- At least 13 years old
- Must have received PCP prevention medicines at any time within three months of study entry
- Must be taking antiretroviral medicines at the time of study entry

Not allowed:

- Use of immunomodulators, such as interleukins, interferons or corticosteroids within 60 days of study entry
- Symptoms or clinical findings suggesting active PCP within 14 days prior to study entry
- Fever for more than two weeks or candidiasis (thrush) observed at study screening
- Need for chronic treatment with any medicines with known anti-PCP activity, such as clarithromycin, atovaquone, pentamidine, dapsone, TMP-SMX, trimethoprim, pyrimethamine or primaquine

Location:

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

UCSF AIDS Clinic
David Gary, RN
(415) 476-9296, ext. 354

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

103. PML Treatment: Cidofovir

Title:

ACTG 363: Pilot Study on the Effect of Cidofovir for the Treatment of Progressive Multifocal Leukoencephalopathy (PML) in Patients with Acquired Immunodeficiency Syndrome (AIDS)

Type of treatment:

Cidofovir: antiviral

Purpose:

To see if cidofovir is safe, well-tolerated and effective in treating PML, an infection of the brain caused by JC virus.

About the study:

During the screening period, patients will have an MRI of the brain. An MRI gives a detailed look at the brain. Patients will also have a lumbar puncture (spinal tap). All patients will receive cidofovir. Cidofovir is given by infusion into a vein. Patients will be in the clinic for about six hours on the days they receive cidofovir. Cidofovir is given once a week for the first two weeks, then once every other week until the end of the study. Within two days before each dose of cidofovir, patients will have blood and urine tests as well as an eye exam. At Weeks 4, 8, 12, 16, 20 and 24, patients will have a neurological examination. At Weeks 8 and 24, patients will have another MRI of the brain and another lumbar puncture. The study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Symptoms of PML for 90 days or less
- MRI of the brain showing focal white matter abnormalities
- CSF positive for JCV, or brain biopsy showing PML

Not allowed:

- Acute opportunistic infections other than KS of the skin
- Neurological exam suggesting other conditions, such as stroke, herpes simplex encephalitis or trauma
- CAT scan or MRI that show enhancing mass lesions
- CSF positive for CMV, bacteria, mycobacteria or fungus
- Past or current uveitis
- Past use of cidofovir
- Use of immunomodulators, such as interferons or interleukins, within 90 days of study entry
- Use of IV pentamidine, foscarnet or amphotericin B within seven days of study entry
- Women who are pregnant or breastfeeding
- Use of investigational antiretroviral drugs with activity against viruses other than HIV within 30 days of study entry

Location:

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

104. PML Treatment: Topotecan

Title:

104864-A: An Open, Comparative, Phase II Study of Intermediate versus Deferred Treatment with Topotecan HCl Given as a Continuous 21-Day Infusion Every 28 Days to Patients with AIDS-Related Progressive Multifocal Leukoencephalopathy (PML)

Type of treatment:

Topotecan: cellular inhibitor

Purpose:

To see if topotecan is effective in treating PML by observing response rate, the response duration, the time to response and the time to progression of PML.

About the study:

Patients are assigned by chance to receive Topotecan right away or to wait. Topotecan is given by infusion into a vein continuously for 21 days (one cycle). A cycle is repeated every 28 days. Study visits are once a week and patients will be on this study until significant improvement or progression of PML lesions is observed. Those patients assigned to delayed treatment will be monitored at least once a week and if their disease gets worse, they will be given the choice of switching to topotecan or be taken off the study. All patients are required to have a brain biopsy and a lumbar puncture (spinal tap).

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Brain biopsy-proven PML
- Stable (no changes) antiretroviral therapy for at least three weeks prior to study entry
- Clinical symptoms consistent with a diagnosis of PML
- Patients with a CD4 count of less than 200, or a prior episode of PCP, must be taking medicine to prevent PCP

Not allowed:

- Prior treatment for PML prior to study entry, including Ara-C
- Use of chemotherapy within 30 days prior to study entry
- Active, untreated syphilis
- Serious opportunistic infections requiring therapy, such as PCP or active MAC
- Active CMV infections requiring ganciclovir or foscarnet
- Any current or past CNS disease, such as toxoplasmosis, cryptococcal meningitis, CNS lymphoma
- Women who are pregant or breastfeeding

Location:

Institute for HIV Research & Treatment
CPMP - Davies Campus
Steve Collinson, RN
(415) 565-6660

105. Prurigo Nodularis: Thalidomide

Title:

Thalidomide for the Treatment of Refractory Prurigo Nodularis and Photodermatitis in Patients With HIV Infection

Type of treatment:

Thalidomide: cytokine inhibitor, antiwasting

Purpose:

To see if thalidomide is safe and effective as a treatment for itchy bumps on the skin associated with HIV infection. These bumps must be diagnosed as "Prurigo Nodularis" and not have responded to any other treatment.

About the study:

Patients are assigned by chance to receive one of two doses of thalidomide. All patients will take real thalidomide. A skin biopsy is required at the beginning and at the end of the study. A skin biopsy is the removal of a small piece of skin. The study lasts one year and study visits are every month. Blood will be drawn every three months.

Required:

- CD4 (T-cell) range: not specified
- HIV positive
- Prurigo nodularis (itchy skin bumps proven by biopsy) that have not gone away with steroid treatment
- 18 years of age or older

Not allowed:

- Pregnant or nursing women
- Moderate-severe peripheral neuropathy
- Currently taking ddC, d4T or systemic chemotherapy

Location:

SFGH Dermatology
Toby Maurer, MD
(415) 206-8680

106. HIV Wasting Treatment: Nandrolone Decanoate

Title:

A Randomized, Double-Blind, Placebo-Controlled Study of Nandrolone Decanoate for HIV-Associated Wasting

Type of treatment:

Nandrolone Decanoate: anabolic steroid

Purpose:

To see if nandrolone decanoate is a safe and effective treatment for weight loss in people with HIV.

About the study:

Patients are assigned by chance to receive an injection of nandrolone decanoate or a placebo injection every week for 12 weeks. Neither patients nor their doctors will know which they are receiving until the study ends. After 12 weeks, all study patients will receive open-label nandrolone decanoate for an additional 12 weeks. Study visits will take place weekly and the study will last 24 weeks. **Patients will be paid $500 for completing this study.**

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Unintended loss of more than 10% of usual body weight
- Normal blood testosterone level
- At least 18 years old

Not allowed:

- Active opportunistic infection
- Use of other steroids, appetite-stimulating drugs or other drugs intended to treat weight loss, including growth hormone, megace, marinol, thalidomide, etc.
- Diarrhea, defined as more than five liquid stools per day
- Treatment for cancer other than KS
- Women who are pregnant or nursing

Location:

UCSF/SFGH Endocrinology
Heather Algren, RN
(415) 206-3319

107. HIV Wasting Treatment: Serostim®

Title:

9037: A Phase IV, Randomized, Parallel Group, Double-Blind, Placebo-Controlled, Dose-Ranging Multicenter Study of Serostim®, Mammalian Cell-Derived Recombinant Human Growth Hormone (r-hGH[m]), in the Treatment of HIV-Associated Catabolism/Wasting

Type of treatment:

Serostim®: human growth hormone

Purpose:

To see if Serostim® is effective in changing physical functioning capabilities in patients with AIDS wasting. To see which dose of Serostim® works best to change lean body mass.

About the study:

Patients are assigned by chance to receive one of two doses of Serostim® or placebo for the first twelve weeks of the study. After 12 weeks, those patients assigned to receive placebo will be assigned by chance to receive one of the two doses of Serostim®. Neither patients nor their doctors will know which they are receiving until the study ends. Serostim® is an injection given under the skin and will be given in the evening (preferably at bedtime). Patients and/or caregivers will be taught how to give injections. Body composition, physical function and quality of life will be evaluated at Weeks 12, 24 and 48. The study lasts about one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Diagnosis of AIDS wasting defined as: unintentional weight loss of at least 10% **or** weight less than 90% of ideal body weight
- Must be receiving at least 100% of the estimated caloric requirement based on a formal nutritional analysis (to be done by the research staff)
- Must be taking an approved antiretroviral therapy for at least 8 weeks prior to study entry and no changes to this treatment during the first 12 weeks of the study

Not allowed:

- Current active opportunistic infections or malignancies, except KS of the skin
- Prior pancreatitis, carpal tunnel syndrome, glucose intolerance, angina, moderate to severe edema, coronary artery disease
- Women who are pregnant or breastfeeding
- Use of radiation therapy, chemotherapy, glucocorticords, or interferons
- Chronic diarrhea, defined as 6 or more liquid stools per day
- Unstable or untreated hypertension
- Active alcohol or substance abuse

Location:

Kaiser San Francisco - HIV Research Unit
Barbara LeMaire, RN, MS
(415) 202-3486

ViRx, Inc. - Palm Springs
Tom Clover, RN
(760) 864-6266

108. HIV Wasting Treatment: Thalidomide

Title:

W002: Compassionate Use of Thalidomde in Adults with HIV-Associated Wasting

Type of treatment:

Thalidomide: cytokine inhibitor, antiwasting

Purpose:

To allow patients who are HIV-infected and are wasting the opportunity to receive treatment with thalidomide.

About the study:

All patients will receive thalidomide for their wasting condition. Patients will be seen in the clinic every two weeks for the first month, then once a month for two months. After 12 weeks of treatment, patients will be evaluated and if further treatment is warranted, will continue taking thalidomide and be seen in the clinic once a month for a maximum of six months. After six months, patients may be re-enrolled if continued treatment is warranted based upon their doctor's evaluation.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Wasting, defined as involuntary weight loss of more than 10% from pre-illness body weight
- Women of childbearing potential must commit to either refraining from reproductive sexual intercourse **OR** to practice **TWO** methods of contraception; one barrier method and one hormonal method

Not allowed:

- Women who are pregnant or breastfeeding
- Severe peripheral neuropathy
- Previously discontinued thalidomide due to noncompliance, intolerance or because of a serious reaction to using thalidomide

Location:

Kaiser San Francisco - HIV Research Unit
Joseph Thatcher, RN, MSN
(415) 202-2529

109. HIV Wasting Treatment: Thalidomide

Title:

W003: An Open Label Study of the Effects of Thalidomide on Body Composition in Adults With HIV-Associated Wasting

Type of treatment:

Thalidomide: cytokine inhibitor, antiwasting

Purpose:

To see what effect thalidomide has on body composition in adults with HIV-associated wasting.

About the study:

All patients will receive thalidomide; there are no placebos in this study. Thalidomide is a pill and taken by mouth. Study visits are every two weeks for the first month, then once a month until week 12, then once every two months until the end of the study. Study visits will consist of exams, blood tests and body composition analysis. The study lasts for 24 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Wasting, defined as involuntary weight loss of more than 5% from pre-illness body weight
- Women of childbearing potential must commit to either refraining from reproductive sexual intercourse **OR** to practice **TWO** methods of contraception; one barrier method and one hormonal method

Not allowed:

- Women who are pregnant or breastfeeding
- Active AIDS-defining opportunistic infections
- Severe peripheral neuropathy

Location:

AltaMed HIV Services
Monica Lopez
(323) 869-5429

St. Luke Medical Group & Clinical Trials
Rebecca Gonzalez
(619) 235-4211

New

110. HIV Wasting Treatment: Thalidomide, Growth Hormone

Title:

Mitigation of Episodic Wasting in HIV Infection

Type of treatment:

Testosterone: steroid
Serostim®: human growth hormone

Purpose:

To see if growth hormone or thalidomide can prevent episodic wasting in HIV patients during secondary infections.

About the study:

Patients are assigned by chance to receive thalidomide or growth hormone or placebo. All patients will receive capsules and daily injections. Neither patients nor their doctors will know which they are receiving until the study ends. Patients will take study medications for four weeks and have five study visits to the General Clinical Research Center at San Francisco General Hospital for body weight, energy expenditure and protein synthesis rate measurements. **Patients will be paid $500 for completing the study.**

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- New diagnosis of one of the following: bacterial pneumonia, sinusitis or bronchitis; pyelonephritis; PCP; tuberculosis, MAC; cryptococcal pneumonia or meningitis; histoplasmosis or cellulitis
- Patients must enroll in the study within three days of beginning treatment for a bacterial infection or within five days of beginning treatment for mycobacterial or fungal infection

Not allowed:

- Women who are pregnant or breastfeeding
- Use of anabolic drugs such as growth hormone or steroids (except stable
- Any cancers other than KS of the skin
- Moderate to severe peripheral neuropathy
- Uncontrolled high blood pressure, diabetes or congestive heart failure

Location:

UCSF/SFGH Endocrinology
Heather Algren, RN
(415) 206-3319

111. HIV Wasting Treatment in Women: Oxandrolone

Title:

BTG/OXN-95-007: A Phase III Randomized, Double Blind Placebo Controlled Study to Determine the Safety and Efficacy of Oxandrolone on Body Weight and Composition in HIV-Infected Women

Type of treatment:

Oxandrolone: anabolic steroid

Purpose:

To see if oxandrolone is safe and to see its effect on body weight and body composition in HIV-infected women.

About the study:

Patients are assigned by chance to receive one of two doses of oxandrolone or placebo. Oxandrolone is in pill form and two pills are taken every day before breakfast. Neither patients nor their doctors will know which they are taking until the study ends. After 12 weeks, all patients will take open label (real) oxandrolone. Initially study visits will be once a week, then once a month. The study lasts 36 weeks. Some locations may pay patients for their participation.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- **Female** patients only
- Documented involuntary weight loss of 10 - 20 % of average body weight
- If taking antiretroviral medications, must be on a stable dose for at least six weeks prior to enrollment

Not allowed:

- Male patients
- Weight loss of greater than 5% during the month prior to enrollment
- Current opportunistic infections
- Use of appetite stimulants or weight promoting agents within four weeks of study entry; such as Megace, Marinol, prednisone, testosterone, growth hormone
- Active alcohol or substance abuse
- Anorexia nervosa or bulimia
- Any cancers other than KS which require chemotherapy
- Ongoing chronic diarrhea defined as more than 3 liquid stools per day at least 4 days per week for more than 2 weeks
- Women who are pregnant or breastfeeding

Location:

AIDS Healthcare Foundation
Deewee McDermott, RN
(213) 913-3953

New

112. HIV Weight Loss Treatment: Nandrolone Decanoate

Title:

A Randomized, Double-Blind, Placebo-Controlled Study of Nandrolone Decanoate for HIV-Associated Weight Loss

Type of treatment:

Nandrolone Decanoate: anabolic steroid

Purpose:

To see if an anabolic steroid, nandrolone decanoate, can increase weight and lean tissue in people with HIV-associated weight loss.

About the study:

Patients are assigned by chance to receive nandrolone decanoate or placebo for 12 weeks. Nandrolone decanoate and placebo are given by injection into a muscle once a week. After the 12-week placebo-controlled part of the study, all patients will receive open-label (real) nandrolone decanoate for an additional 12 weeks. Response wil be measured by body weight and composition. Nutritional intake, HIV disease progression and immunological status will also be measured. Injections and weight checks are once a week and study visits are every six weeks. The study lasts for 24 weeks. **Patients will be paid $500 for completing the study.**

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Documented unintentional weight loss of 5% or more
- Normal blood testosterone level within four weeks of study entry

Not allowed:

- Any active infection within 30 days of study entry
- Use of other appetite-stimulating, anabolic, hormonal or experimental treatment (including growth hormone, megace, marinol, steroids, thalidomide, interleukins) within 30 days of study entry
- Current cancers requiring treatment except KS
- Starting or changing antiretroviral medications within 30 days of study entry
- Diarrhea, defined as more than 5 liquid stools per day while using antidiarrheal medication
- Positive pregnancy test during study screening

Location:

UCSF/SFGH Endocrinology
Heather Algren, RN
(415) 206-3319

113. HIV Weight Loss in Women: Nandrolone Decanoate

Title:

ACTG 329: A Randomized, Double-Blind, Placebo-Controlled, Phase I/II Trial of Nandrolone Decanoate in Women With HIV-Associated Weight Loss

Type of treatment:

Nandrolone Decanoate: anabolic steroid

Purpose:

To see if nandrolone decanoate is a safe and effective treatment for women experiencing HIV-associated unintentional weight loss.

About the study:

Women will be assigned by chance to receive nandrolone decanoate or placebo. Nandrolone decanoate is given by injection into a muscle. Neither patients nor their doctors will know which they are receiving until the study ends. After 12 weeks, all patients will be eligible to receive open-label (real) nandrolone decanoate for an additional 12 weeks. Injections are given every two weeks. The study lasts 24 weeks. Patients in this study will receive body composition tests. Some locations may pay particcipants for their participation.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 13 years old
- Female
- Documented weight loss of >5% within the previous 12 months
- Patients taking antiretroviral therapy must have been on stable (no changes) therapy for at least 30 days prior to study entry

Not allowed:

- Males
- Active opportunistic infection or other major illness within 30 days of study entry
- Use of other anabolic therapy, such as steroids, growth hormone, thalidomide, megace, marinol, within 30 days of study entry
- Starting antiretroviral therapy within 30 days of study entry
- Women who are pregnant or breastfeeding
- Patients with a persistent palpable dominant breast mass at study entry that has not been evaluated
- Any history of cervical cancer. Patients with a high grade SIL or CIN2 or worse Pap smear are not eligible
- Diabetes mellitus

- Current or past congestive heart failure or cardiomyopathy
- Any condition requiring anticoagulation therapy while on study
- Persistent diarrhea, nausea, vomiting or impaired oral intake

Location:

LAC-USC Medical Center ACTU
Frances Canchola, RN
(323) 343-8281

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

114. HIV Wasting Syndrome: Observational

Title:

The Role of Malabsorption and Energy Deficit of the AIDS Wasting Syndrome

Type of treatment:

Observational: none

Purpose:

To compare the treatment of malabsorption and energy expenditure in patients with weight loss and those without weight loss.

About the study:

Participants will spend six to seven inpatient days in the General Clinical Research Center at San Francisco General Hospital. During their hospital stay, patients will have their diet monitored and their stools (feces) will be collected for analysis. Patients will also undergo blood tests and energy expenditure tests during their stay. All patients must have an endoscopy and sigmoidoscopy (internal examinations of the digestive tract) with biopsies (tissue samples taken) before enrolling in the study. There are five outpatient visits after the inpatient stay. The study lasts three weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Patients with or without weight loss will be allowed to participate

Not allowed:

- Active opportunistic infections
- Treatable gastrointestinal infections

Location:

Division of Gastroenterology at SFGH
Jamey Maimares, RD
(415) 206-4748

115. HIV Weight Loss: Observational

Title:

Energy Balance and Wasting Syndrome

Type of treatment:

Observational: none

Purpose:

To study metabolism and collect data from patients with HIV weight loss.

About the study:

Patients joining this study should be experiencing some weight loss associated with HIV disease. There are two options for this study, inpatient or outpatient. The inpatient study requires four days in the hospital for metabolic rate testing and two outpatient visits. The **inpatient** study lasts three weeks and **patients will be paid $400** for completing the study. The outpatient study requires three days of **outpatient** visits one week apart and those **patients will be paid $250** for completing the study.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Male patients only

Not allowed:

- Females

Location:

San Francisco VA Medical Center
Mae Pang, RN, MS
(415) 750-2005

116. Lean Body Mass: Observational

Title:

ACTG 892: Effect of Highly Active Antiretroviral Therapy on Lean Body Mass

Type of treatment:

Observational: none

Purpose:

To see if a decrease in HIV viral load has any effect on lean body mass.

About the study:

This study is open to patients currently enrolled in an ACTG antiretroviral trial. Patients will have study visits every two months and these visits will coincide with the study visits for the antiretroviral trial. Patients will be weighed, have lean body mass checked by BIA (bioelectrical impedance analysis) and fill out questionnaires. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 10,000 copies/mL
- HIV positive
- At least 18 years old
- Entry into an ACTG antiretroviral therapy trial

Not allowed:

- Acute infection or illness within 14 days of study entry
- Fever greater than 101.3 F within 14 days of study entry

- Current chemotherapy for cancers other than KS
- Diabetes requiring oral or insulin therapy
- Any therapy designed to improve appetite or weight gain, such as megace, thalidomide, marinol or growth hormone within 30 days of study entry
- Diarrhea defined as four or more liquid stools per day while using antidiarrheal medication within 14 days prior to study entry
- Women who are pregnant or breastfeeding

Location:

Stanford University Medical Center
Sandra Valle, PA-C
(650) 723-8169

UCSD Treatment Center
Screening Nurse
(619) 543-8080

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

New

117. Anabolic Therapies and Metabolism: Growth Hormone, Nandrolone Decanoate

Title:

Anabolic Therapies and their Metabolic Effects in AIDS

Type of treatment:

Nandrolone Decanoate: anabolic steroid
Serostim®: human growth hormone

Purpose:

To evaluate the effects of growth hormone and nandrolone decanoate on regional fat content, sugar and fat metabolism, HIV viral load, and thymus function in HIV-infected patients who have experienced alterations in their body shape.

About the study:

Patients who have experienced changes in the shape of their bodies will be evaulated by an endocrinologist to see if they are eligible. Eligible patients will be hospitalized in the General Clinical Research Center at San Francisco General Hospital for five days to undergo detailed sugar and fat metabolism studies and to measure total and regional fat content. After completing these tests, patients will begin a six-month treatment course of either nandrolone decanoate or growth hormone. Patients will know which treatment they are receiving. Patients will return to the General Clinical Research Center periodically for follow-up. The study lasts at least six months and **patients will be paid $1,200** for completing the study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: average of two values must be less than 5,000 copies/mL when measured twice in the preceeding month
- HIV positive
- Evidence of fat accumulation, such as abdominal obesity or buffalo hump in the neck and/or peripheral fat loss (lipodystrophy)
- Between 30 and 50 years old

Not allowed:

- Diabetes mellitus
- History of cardiovascular disease
- Use of testosterone, DHEA, megace, thalidomide, ketoconazole, lipid-lowering medicines, hypoglycemic medicines, growth hormone or nandrolone decanoate within 30 days of study entry

Location:

UCSF/SFGH Endocrinology
Joan Lo, MD
(415) 206-4430

New

118. Metabolism and Protease Inhibitor Therapy: Observational

Title:

Effects of Initiation of Protease Inhibitor Therapy on Metabolism and Body Composition

Type of treatment:

Observational: none

Purpose:

To see what effects protease inhibitors have on sugar and fat metabolism and on body composition in patients who are starting protease inhibitor treatment.

About the study:

Patients who are about to start treatment with a protease inhibitor will be hospitalized in the General Clinical Research Center at San Francisco General Hospital for five days of detailed studies of sugar and fat metabolism and measurements of total and regional fat content. After completing these measurements, patients will begin their antiretroviral treatment, which includes a protease inhibitor and return to the General Clinical Research Center periodically over the next 18 months for follow-up measurements. **Patients will be paid $2,000 for completing this study.**

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Body mass index less than 27 kg/m2 (to be calculated by research staff)

Not allowed:

- Women who are pregnant or breastfeeding
- Prior use of any protease inhibitors
- Diarrhea, defined as 6 or more stools per day
- Persistent nausea or vomiting
- Diabetes mellitus
- Use of anabolic medicines, appetite stimulants, parenteral or tube feeding, or initiation of treatment for a systemic infection within 30 days of study entry. Patients on stable testosterone replacement therapy for at least 60 days prior to study entry are allowed.

Location:

UCSF/SFGH Endocrinology
Kathleen Mulligan, PhD
(415) 206-5882

119. Nutrition in Women with HIV: Observational

Title:

Nutritional Assessment of Women Living with HIV

Type of treatment:

Observational: none

Purpose:

To learn about the effect of HIV disease on women's body composition (fat, muscle and bone). To learn how HIV disease affects the amount of energy used up by a woman's body when it is at rest. To learn how HIV disease affects women's eating habits. To compare these factors in women and men.

About the study:

This study consists mainly of body measurements and interviews. Every six months, patients come into the clinic for a two-hour study visit. Tests and measurements are done to determine body composition and patients are asked questions about the kind and amount of food they eat. Nutritional counseling is offered to patients who want it. The study lasts for an indefinite length of time. **Patients are paid $25 at each visit.**

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- **Female**

Not allowed:

- Males

Location:

UCSF/SFGH Endocrinology
Viva Tai, RD, MPH
(415) 206-4090

120. Human Herpes Virus 8 Project: Developmental

Title:

Pilot Project for the Development of a Branched-Chain DNA Assay for Human Herpes Virus 8

Type of treatment:

Observational: none

Purpose:

To see whether a laboratory test can be developed to detect and measure the amount of human herpes virus 8 in patients' blood samples.

About the study:

Patients with KS will be asked to provide one blood sample at one visit. **Patients will be paid $25 for this one visit.**

Required:

- CD4 cell (T-cell) range: not specified
- At least 13 years old
- Must have a diagnosis of Kaposi's sarcoma

Not allowed:

- No exclusions

Location:

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

121. HIV Transmission: Educational Intervention

Title:

HIV Prevention Intervention Study with an Embedded Observational Substudy

Type of treatment:

Observational: none

Purpose:

To evaluate a behavioral intervention for heterosexual HIV-discordant couples and to identify biological factors that might be associated with prevention of HIV transmission in women who have been sexually exposed to HIV, but who remain uninfected.

About the study:

The main study is one year long and consists of a brief intensive intervention (one hour per week over four weeks) followed by two 30-minute booster sessions over a period of three months. Couples will be assigned by chance to receive intensive counseling for both partners or intensive counseling for the infected partner, with support and referrals for the negative partner. Participants will be seen at various locations throughout the Bay area. Every 6 months, participants will also be seen for a 2-hour study visit with interviews and lab tests for HIV, STD

and pregnancy. The biological substudy consists of a brief visit at San Francisco General Hospital with a short survey, collection of blood, urine and semen samples and a brief pelvic examination for the women. The study lasts three years. Participants are paid for their participation.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive with an HIV-negative partner of the opposite sex **or** HIV negative with an HIV-positive partner of the opposite sex
- Sexually active with that partner
- At least 18 years old

Not allowed:

- Unable to speak English or Spanish

Location:

California Partners Study
Jason Coloma
(415) 597-9194

122. Pharmacokinetics: AZT, Oral/Injectable Contraceptives

Title:

ACTG 317: The Effect of Oral and Injectable Contraceptives (Norethidrone/Ethinyl Estradiol, Medroxyprogestrone Acetate) and Gender on Plasma and Intracellular Zidovudine Pharmacokinetics

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Ortho Novum: oral contraceptive
Depo-Provera: injectable contraceptive

Purpose:

To see if mens' and womens' bodies process AZT differently (Part A). To see if taking birth control pills or an injectable birth control agent has any effect on the way AZT is processed by womens' bodies (Part B).

About the study:

Both men and women will participate in Part A. All patients will take AZT by mouth three times a day, along with their other antiretroviral medications, for the first seven days. On Day seven, some patients will receive AZT through a vein in the morning and two doses of AZT by mouth later in the day. On Day 8, those patients who took AZT by mouth on Day 7 will take AZT through a vein in the morning and two doses by mouth later in the day. On the day they receive AZT through a vein (either Day 7 or Day 8), multiple blood and urine tests will be collected throughout the day. Male patients will discontinue study treatment and return for a final visit within seven days after Day 8. Females will resume their pre-study medication(s) and move on to Part B. Women in Part B will choose either oral (Ortho Novum 1/35) or injectable (Depo-Provera) contraceptive and begin taking it at the onset of their next menstrual cycle following Part A. Between Days 7-11 after the start of their **next** menstrual period (after beginning birth control), women will resume taking AZT as they did in part A with a dose of AZT given through a vein either on Day 7 or Day 8 and have the same blood and urine tests as in part A. Women will return for a final visit within seven days of Day 8. **THE STUDY IS CURRENTLY ENROLLING WOMEN ONLY.**

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 45 years old
- At least 60 days or more of therapy with AZT alone or in combination with 3TC, ddI, ddC, or 3TC + indinavir, up to seven days prior to study entry
- Women must have regular menstrual cycles, defined as a 25-35 day interval with usual amounts of bleeding
- Women must enter Part A between 10-18 days since the first day of their last menstrual period (LMP)

Not allowed:

- Women receiving oral or injectable contraceptives for the past three months
- Current use of any NNRTIs, such as delavirdine or nevirapine
- Past intolerance of 600mg/day AZT
- Past or current hypertension (> 140/90 mm Hg)
- Past thrombophlebitis or pulmonary emboli
- Any cancers including KS

Location:

UCSF AIDS Program at SFGH/ACTU
David Gary, RN
(415) 476-9296, ext. 354

123. Pharmacokinetics: INH

Title:

Pharmacokinetics of Antituberculous Agents in HIV

Type of treatment:

Isoniazid: antimycobacterial

Purpose:

To learn how INH is absorbed and processed in the body. To compare the way this happens in men and women, and in people with AIDS and those who do not have HIV Infection.

About the study:

This study is open to men and women with AIDS and men and women who do not have HIV infection. All patients take 300 mg. of INH every day for five days. Blood is drawn to measure the amount of INH in the blood. A small tube is inserted into the lungs to collect fluid and cells in order to measure the amount of INH that is absorbed into the lungs. There are several short study visits and one six-hour study visit. **Patients are paid $350 for completing the study.**

Required:

- CD4 cell (T-cell) range: not specified
- At least 18 years old
- AIDS **or** HIV-negative
- Negative PPD (skin test for TB), negative chest x-ray for patients with HIV

Not allowed:

- Diarrhea, abdominal pain or cramping, nausea, vomiting
- HIV positive, but not meeting the CDC definition for AIDS
- Women who are pregnant or breastfeeding

Location:

UCSF Infectious Diseases Research
Juliana Kipps, RN
(415) 476-5398 **OR**
Mari McQuitty, RN
(415) 476-2308

124. Pharmacokinetics: Indinavir, Rifabutin

Title:

ACTG 365: Steady-State Pharmacokinetic Interaction Study of Indinavir and Rifabutin

Type of treatment:

Indinavir: antiretroviral, protease inhibitor
Rifabutin: antimycobacterial

Purpose:

To see how the body processes indinavir and rifabutin when they are taken at the same time and at different times. To see if it is safe to take these two drugs together.

About the study:

Patients are assigned by chance to be in one of two groups. Patients in **Group A** will take study drugs for six weeks; patients in **Group B** for four weeks. Group A patients will take rifabutin by itself for the first two weeks, then indinavir and rifabutin for the next four weeks. Patients in Group B will take indinavir by itself for the first two weeks followed by indinavir plus rifabutin for an additional two weeks. Study visits are once a week and there are three 24-hour study days (two for Group B) where patients will have multiple blood draws. The study lasts seven weeks for Group A and five weeks for Group B.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 60 years old
- Patients must take at least one antiretroviral nucleoside analog, such as AZT, ddC, 3TC or d4T. ddI is not allowed during the study

Not allowed:

- Active opportunistic infections
- Women who are pregnant or breastfeeding
- Use of ddI during the study
- Prior use of indinavir for Group A; prior use of indinavir is allowed for Group B
- Use of rifampin, triazolam, midazolam, astemizole, nevirapine, phenobarbital or any investigational drug within 14 days of study entry
- Patients requiring maintenance therapy for active opportunistic infections, except acyclovir for herpes simplex
- Active alcohol or substance abuse
- Past episode of kidney stones

Location:

LAC-USC Medical Center ACTU
Connie Funk, RN
(323) 343-8282

New

125. Chronic Cancer Pain Management: Dilaudid SR

Title:

DO-104: A Repeated-Dose Evaluation of Analgesic Use and Safety of Dilaudid SR (Hydromorphone HCl) in Patients with Chronic Cancer Pain

Type of treatment:

Dilaudid SR: analgesic

Purpose:

To develop recommended dosing information for starting treatment with Dilaudid SR in patients who are switching from other strong oral or skin patch opioid medications.

About the study:

During the screening phase of the study, patients will be stabilized on their prior oral or skin patch medications for three consecutive days. Patients will then be switched to Dilaudid SR once daily. The dose of Dilaudid SR will be changed after every two days until a stable dose of Dilaudid SR has been found. Patients will then be followed for two weeks on a maintenance dose. Patients completing the study will be eligible for participation in a long-term extension study with Dilaudid SR. The study lasts from 20 to 30 days.

Required:

- HIV status: not applicable
- Chronic cancer pain and receiving strong oral or skin patch poioid medications
- At least 18 years old
- Patients who requite at least 45 mg or oral morphine or opioid equivalent every 24 hours for the management of chronic cancer pain

Not allowed:

- Intolerance or hypersensitivity to hydromorphone
- Patients who have dysphagia or are unable to swallow pills
- Women who are pregnant or breastfeeding
- Use of any investigational drug within 30 days of study entry
- Active blood loss or bleeding disorder

Location:

ViRx, Inc. - Palm Springs
Tom Clover, RN
(760) 864-6266

New

126. Chronic Non-Malignant Pain Management: Dilaudid SR

Title:

DO-105: A Repeated-Dose Evaluation of Analgesic Use and Safety of Dilaudid SR (Hydromorphone HCl) in Patients with Chronic Non-Malignant Pain

Type of treatment:

Dilaudid SR: analgesic

Purpose:

To develop recommended dosing information for starting treatment with Dilaudid SR in patients who are switching from other strong oral or skin patch opioid medications.

About the study:

During the screening phase of the study, patients will be stabilized on their prior oral or skin patch medications for three consecutive days. Patients will then be switched to Dilaudid SR once daily. The dose of Dilaudid SR will be changed after every two days until a stable dose of Dilaudid SR has been found. Patients will then be followed for two weeks on a maintenance dose.

Patients completing the study will be eligible for participation in a long-term extension study with Dilaudid SR. The study lasts from 20 to 30 days.

Required:

- HIV status: not applicable
- Chronic non-malignant pain, including AIDS-associated pain, and receiving strong oral or skin patch poioid medications
- At least 18 years old
- Patients who requite at least 45 mg or oral morphine or opioid equivalent every 24 hours for the management of chronic non-malignant pain

Not allowed:

- Intolerance or hypersensitivity to hydromorphone
- Patients who have dysphagia or are unable to swallow pills
- Women who are pregnant or breastfeeding
- Use of any investigational drug within 30 days of study entry
- Active blood loss or bleeding disorder

Location:

ViRx, Inc. - Palm Springs
Tom Clover, RN
(760) 864-6266

127. Pharmacokinetics in Pregnant Women: HAART

Title:

The Pharmacology of Antiretroviral Therapy During Pregnancy

Type of treatment:

HAART: antiretrovirals, including at least one protease inhibitor

Purpose:

To see how womens' bodies process highly active antiretroviral therapy during pregnancy.

About the study:

Pregnant women will spend one 8-hour day per trimester at the research clinic for multiple blood draws. Patients will have a catheter inserted into a vein to reduce the number of needle sticks during blood draws. Patients will be on this study for the duration of their pregnancy.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Pregnant, at least six weeks gestation
- Must be taking stable (no changes) highly active antiretroviral therapy (HAART) that includes at least one protease inhibitor, for at least two weeks prior to study entry

Not allowed:

- Women with a history of a life-threatening event associated with antiretroviral therapy
- Active alcohol and/or substance abuse

Location:

UCSF Drug Research Unit at SFGH
Sandra Hayashi, Pharm.D.
(415) 476-6870

128. Mother-Newborn Transmission Prevention: Nevirapine

Title:

Pediatric ACTG 316: A Phase III Randomized, Blinded Study of Nevirapine versus Nevirapine Placebo for the Prevention of Maternal-Fetal Transmission in Pregnant HIV-Infected Women Who Present During the Third Trimester of Pregnancy

Type of treatment:

Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To find out if taking nevirapine during labor prevents infants of HIV-infected mothers from becoming infected with HIV.

About the study:

HIV-infected pregnant women will be assigned by chance to receive nevirapine or placebo during labor. Nevirapine and its placebo are taken by mouth. Women will take a single dose of nevirapine (or its placebo) during active labor. The newborn infant will also receive a single dose of nevirapine (or placebo) between 48 and 72 hours after it is born. Mothers will be encouraged to also take AZT during their pregnancy (in accordance with US Public Health Service guidelines). Mothers and their infants will have follow-up study visits at one month, 3 months and 6 months after the infant is born.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive pregnant women
- At least eight months pregnant

Not allowed:

- Prior use of nevirapine, delavirdine or any other non-nucleoside reverse transcriptase inhibitor
- Participation in any other perinatal treatment study

Location:

Bay Area Perinatal AIDS Center (BAPAC)
Maureen Shannon, FNP / CNM
(415) 206-8919

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Maureen Shannon, FNP / CNM
(415) 206-8919

New

129. HIV Infection in Pregnant Women and Infants: Fortovase™, AZT, 3TC

Title:

Pediatric ACTG 386: A Phase I Trial of the Safety and Pharmacokinetics of Fortovase™ (Saquinavir-SGC) Co-Administered with ZDV and 3TC in HIV Seropositive Pregnant Women During Gestation and Postpartum, and in Their Infants Post Maternal Dosing

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Fortovase™: antiretroviral, protease inhibitor

Purpose:

To see if the combination of AZT, 3TC and Fortovase™ (soft gel saquinavir) is safe and has any effect on HIV viral load in pregnant women. To see how much Fortovase™ is in the blood of pregnant women prior to giving birth, during labor, after giving birth, and to see if any was passed on to the baby at the time of birth. The baby will not receive any Fortovase™ during the study but will receive AZT and 3TC.

About the study:

Mothers will begin taking Fortovase™, AZT and 3TC. These medications are taken by mouth and mothers will continue taking them up through 12 weeks after their babies are delivered. Study visits during pregnancy are at Week 2, then every four weeks until active labor. During active labor, mothers are given an extra dose of Fortovase™ by mouth and AZT will be given by infusion into a vein until the umbilical cord is closed off. After delivery, mothers resume all medications by mouth for an additonal 12 weeks, with study visits at Weeks 6 and 12 post delivery. Babies will take liquid AZT and 3TC by mouth for six weeks. Babies will be seen at the clinic at 1, 6, 12 and 24 weeks after birth.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive women
- Pregnant with a gestational age of 14 to 32 weeks for single pregnancies; and 14 to 30 weeks for twin births, base on menstrual history and confirmed by ultrasound

- At least 13 years old or local IRB age of consent
- Normal ultrasound

Not allowed:

- Prior use of saquinavir
- Treatment with 3TC prior to pregnancy **OR** more than three weeks treatment during pregnancy
- Use of any NNRTIs (delavirdine, nevirapine, efavirenz) within three weeks of study entry
- Active alcohol and/or substance abuse
- Active opportunistic infections or serious bacterial infections at time of study entry
- Participation in any therapeutic or vaccine perinatal study during this current pregnancy
- Chronic malabsorption or chronic diarrhea
- Women who intend to breastfeed their babies

Location:

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

130. HIV Infection in Pregnant Women and Infants: Nelfinavir, AZT, 3TC

Title:

Pediatric ACTG 353: A Phase I Trial of the Safety, Tolerance and Pharmacokinetics of Oral Nelfinavir (Viracept®) Co-Administered with Zidovudine (ZDV) and Lamivudine (3TC) in HIV-Infected Pregnant Women and Their Infants

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if nelfinavir is safe and effective in treating HIV infection when given in combination with AZT and 3TC to pregnant women. To see how nelfinavir is processed in pregnant womens' bodies and to see how it is processed in the newborn infant.

About the study:

Participants will receive AZT, 3TC and nelfnavir from the start of the study until 12 weeks after delivering their babies. Women will come to the clinic every two weeks until week 36 of their pregnancy, then once a week until the start of labor. Mothers will have ultrasound performed between 18 and 20 weeks of pregnancy and every four weeks after week 26 of pregnancy. After taking study drugs for about two weeks, mothers will have a nine-hour study visit for multiple blood draws. Mothers in active labor will receive their AZT by infusion into a vein. Newborn babies will being taking nelfinavir, AZT and 3TC when they are able to take liquids and continue taking study medications for six weeks. Babies will have study visits at 8 days, 3 weeks, 6 weeks, 3 months and 6 months of life.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Pregnant with a gestational age of at least 14 weeks but no more than 34 weeks, based upon menstrual history and confirmed by ultrasound or sonograph

Not allowed:

- Past use of any protease inhibitors
- Treatment with 3TC prior to pregnancy **OR** more than three weeks treatment during this pregnancy
- Use of NNRTIs, such as delavirdine, nevirapine or Sustiva®, within two weeks of study entry
- Active alcohol or substance abuse
- Active opportunistic infections
- Chronic malabsorption or diarrhea

Location:

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

131. HIV Infection in Pregnant Women: d4T, 3TC

Title:

Pediatric ACTG 332: A Phase I/II Open Label Study To Evaluate the Safety, Tolerance and Pharmacokinetics of Stavudine (d4T) in Combination with Lamivudine (3TC) in HIV Infected Pregnant Women and Their Infants

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see how d4T is processed by women's bodies after the first trimester, through labor and delivery and to see how d4T is processed by their infants' bodies. To see what effect the combination of d4T and 3TC has on HIV viral load in pregnant women and their infants.

About the study:

Pregnant women in this study will take 3TC and d4T during pregnancy, labor and delivery. After delivery, infants will be divided into two groups: those whose mothers will allow them to receive AZT and those whose mothers will not allow them to receive AZT. Infants in Group 1 will receive AZT, 3TC and d4T; those in Group 2 will receive 3TC and d4T. AZT and 3TC are given to Group 1 babies by mouth

for six weeks and d4T is given by mouth when the baby is 6 and 42 days old. Babies in Group 2 will receive d4T and 3TC by mouth every day for six weeks. Babies will be examined and have blood tests done eight weeks after medication is stopped and when they are six months old.

Required:

MOTHERS

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Intolerance of or refusal to take AZT
- Gestational age of 14-34 weeks by menstrual history or screening ultrasound

INFANTS

- Born to HIV-infected mothers who have received d4T/3TC as per study design

Not allowed:

MOTHERS

- Any acute infection within 14 days of study entry
- Severe peripheral neuropathy
- Uncontrollable diarrhea
- Current alcohol or substance abuse
- Mothers who plan to breastfeed their infants
- Use of antiretroviral or immunomodulatory medicines other than study drugs

INFANTS

- Infants who are unable to take medication by mouth or who have serious life-threatening illnesses

Location:

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

New

I32. HIV Infection in Pregnant Women: Observational

Title:

Pediatric ACTG 367: Medical Chart Abstraction of HIV-Infected Pregnant Women and Their Infants Receiving Care or Consultation at Study Sites

Type of treatment:

Observational: none

Purpose:

To obtain general information and characteristics about HIV-infected pregnant women and their babies who have been (are being) seen at study sites. This information will be used to help design future studies for HIV-infected pregnant women.

About the study:

All information collected for this study will come from the mothers' and infants' medical charts. Some of the data to be collected includes information about prenatal care, laboratory tests pertaining to HIV infection, medical history, obstetrical history, and use of anti-HIV medications during the pregnancy and the outcome of the pregnancy. All information collected is confidential and will not be linked to mothers' and babies' names.

Required:

- HIV positive pregnant women
- Receiving care at a study site during the study period
- Infants born to study mothers

Not allowed:

- No exclusions

Location:

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

I33. HIV Infection in Women in Labor: AZT

Title:

Pediatric ACTG 324: A Phase I Trial of the Pharmacokinetics and Tolerance of Oral Zidovudine Administered to HIV-1 Infected Pregnant Women During Labor and Delivery

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see how AZT is processed by the body when taken by mouth in HIV-positive women during labor and delivery

About the study:

This study invloves two groups of patients. At the onset of labor, the first group of patients will take three doses of AZT, three hours apart. Blood samples will be taken after each dose. After the last dose of AZT is taken by mouth, patients will take AZT by infusion into a vein until delivery of the baby. If no problems occur with the first group of patients, the second group will follow the same plan, except they will continue taking AZT by mouth after the third dose, rather than taking AZT by infusion into a vein. Patients will return to the clinic one week after delivery, and again four to eight weeks and six to eight months after delivery. Blood samples will be taken at each visit.

Required:

- CD4 cell (T-cell) range: not applicable
- Mothers must be HIV positive
- Mothers must be at least 34 weeks pregnant, confirmed by pelvic exam or ultrasound
- Prior treatment with AZT for at least 28 days during this current pregnancy

Not allowed:

- Use of any antiretroviral other than AZT
- Any active opportunistic or other serious infection at the time of study entry
- Intrauterine growth retardation
- Elective cesarean section
- Participation in any other perinatal treatment trial during this pregnancy

Location:

Bay Area Perinatal AIDS Center (BAPAC)
Maureen Shannon, FNP / CNM
(415) 206-8919

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

UCSF Pediatric Immunology Program
Maureen Shannon, FNP / CNM
(415) 206-8919

134. HIV Exposure in Premature Infants: AZT

Title:

Pediatric ACTG 331: The Safety, Tolerance and Pharmacokinetics of Zidovudine in Premature Infants Exposed to HIV

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To learn how AZT is absorbed and processed in premature infants exposed to HIV. To learn about the safety of using AZT in premature infants.

About the study:

Infants who are born prematurely and who will receive AZT as part of their clinical care will be enrolled in this study. The study requires nine blood samples collected over 30 days, and some additional clinical laboratory tests collected over 12 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- Premature infant (34 weeks gestation or less)
- Less than 5 days old
- Infant should receive AZT, in the opinion of the primary care provider

Not allowed:

- Life-threatening illnesses
- Infant not expected to survive beyond six weeks

Location:

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

135. HIV Infection in Newborns: 1592U89, AZT

Title:

Pediatric ACTG 321: Phase I Study of Safety, Tolerance, and Pharmacokinetics of 1592U89 with Standard Zidovudine (ZDV) Therapy in Neonates Born to HIV-1 Infected Mothers

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
1592U89: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To find out the amount of 1592U89 there is in the blood of newborn babies who receive a single dose of 1592U89 in addition to AZT. To compare the safety of different doses of 1592U89.

About the study:

This is a dose escalating study. This means that the first group of infants entering the study will receive the lowest dose of 1592U89. If no bad side effects are seen, the next group of infants will receive a higher dose of 1592U89. This study consists of two parts: Part 1 and Part 2. Part 1 has two groups: A and B. Group A is for infants 0 - 72 hours of age; Group B is for infants 21-28 days of age. Both groups will receive a single dose of 1592U89 and AZT on the first day. They will continue to take AZT four times a day for six weeks. 1592U89 and AZT are taken by mouth. Five study visits are required for Part 1. Part 2 is a study of multiple doses of 1598U89 in infants 0-72 hours of age. All infants will take 1592U89 and AZT every day for six weeks. Six study visits are required. The study lasts eight weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Infants born to HIV-infected mothers
- **Part 1A**: Infants between birth and 72 hours old
- **Part 1B**: Infants between 21 and 28 days old

Not allowed:

- Infants with major congenital abnormalities
- Exposure (through the mother) to any protease inhibitors or NNRTIs
- Any serious infections requiring treatment during the study

Location:

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

I36. HIV Infection in Infants and Children: I592U89

Title:

CNAA/B3007: 1592U89 Open Label Protocol for Pediatric Patients with HIV Infection

Type of treatment:

1592U89: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To provide access to 1592U89 for infants and children with advanced HIV infection and limited treatment options and to see if 1592U89 is safe and well-tolerated in pediatric patients.

About the study:

All infants and children will receive 1592U89 and it is recommended that 1592U89 be used with other antiretroviral medications. Children must be seen by their doctor once a month for the first two months, then every other month. Children will be in this study until their doctors feel thay are no longer receiving benefits or until the drug is FDA-approved for use in infants and children in the United States.

Required:

- CD4 cell (T-cell) range: less than 15% of the total lymphocyte count **AND**
- Viral load range: more than 30,000 copies/ml or encephalopathy despite at least four weeks of antiretroviral therapy **OR** because no therapy was given due to bad side effects of AZT, 3TC or ddI
- Between 6 months and 14 years old
- No access to any 1592U89 pediatric clinical trial for which the child could qualify
- HIV positive

Not allowed:

- Females that are pregnant
- Severe liver or kidney disease

Location:

Children's Hospital Los Angeles
Sarah Fox-Wheeler, RN
(213) 669-4537

I37. HIV Infection in Infants and Children: 3TC, d4T, Nevirapine, Nelfinavir

Title:

Pediatric ACTG 356: Early Intensive Antiretroviral Combination Therapy in HIV-1 Infected Infants and Children

Type of treatment:

Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To see if the quadruple-drug therapy consisting of 3TC, d4T, nevirapine and nelfinavir is safe and effective in lowering the amount of HIV RNA in the blood to an undectectable amount. To see if these four drugs are safe when used in combination in HIV-infected infants and children.

About the study:

All patients will receive 3TC, d4T, nevirapine and nelfinavir; there are no placebos in this study. There are six study visits for blood tests during the first two weeks of the study. After the first two weeks, patients will have study visits once a month until week 24. Patients whose viral load is still measurable after 16 weeks will discontinue study medications and may be offered a different treatment. They will have study visits every three months for one year. Children whose viral load is not measurable after 16 weeks will remain on study medications through two years. Study vists for these children are once a month for three months, every two months for the rest of that year, then every three months for the second year of the study. The study lasts 104 weeks (2 years).

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 15 days through two years old

Not allowed:

- More than six weeks of prior antiretroviral therapy, or any past infant use of nevirapine, or any mother who used nevirapine for more than two weeks
- Use of any other antiretrovirals, other investigational drugs, immunomodulators or HIV vaccines throughout the study
- Past clinical pancreatitis
- Infant or maternal use of more than one single dose of nelfinavir

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

138. HIV Infection in Infants and Children: Ritonavir, AZT, 3TC

Title:

Pediatric ACTG 345: Phase I/II Study of Ritonavir in HIV-1 Infected Infants and Children

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Ritonavir: antiretroviral, protease inhibitor

Purpose:

To see if ritonavir is safe and well-tolerated when given in single and multiple oral doses, either alone or in combination with AZT and 3TC, to HIV-infected infants and children. Currently, no one knows exactly how much ritonavir should be given to infants and young children. This study, hopefully, will answer these important questions.

About the study:

The first children enrolled to the study will receive ritonavir by itself for seven days, then will be started on ritonavir, AZT and 3TC and be followed for the duration of the study. During the first seven days of the study, blood samples wil be drawn to measure the amount of ritonavir in the patient's blood. The results of these blood measurements will be used to adjust the amount of ritonavir given (either more or less) to the remaining children in the study.

Study visits are every two weeks for the first month, then once a month for 17 months, then once every two months for an additional six months. Some study visits will have multiple blood draws. The study lasts about two years.

Required:

- HIV positive for children 3 months to 2 years old
- HIV exposed or presumed infected for infants less than 3 months old
- Between one month and two years of age

Not allowed:

- Any AIDS-defining opportunistic infection within two months of study entry
- Wasting or failure to thrive
- Any cancers
- Use of antiretrovirals for 6-12 weeks

Location:

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

139. HIV Infection in Infants: ALVAC HIV Vaccine

Title:

Pediatric ACTG 326: A Phase I/II Study to Evaluate the Safety and Immunogenicity of ALVAC HIV Vaccine Alone or with a Subunit Vaccine in Children Born to HIV-Infected Mothers

Type of treatment:

ALVAC Vaccine: vaccine

Purpose:

To see if canarypox HIV ALVAC vaccine is safe and effective in producing an immune response, when used alone or in combination with another vaccine, in infants born to HIV-infected mothers. To see how these vaccines affect the baby's immune system.

About the study:

HIV-infected mothers will be enrolled in this study when they are 37 weeks pregnant or as soon thereafter as possible. Newborn babies will be assigned by chance to receive either the ALVAC vaccine or placebo. Neither parents nor the baby's doctor will know which they are receiving until the study ends. The vaccine and its placebo are given by injection into the baby's thigh within 72 hours of birth and at 1, 2 and 3 months of age. The first two groups of babies will receive only the ALVAC vaccine or placebo. At a later date, when another vaccine product becomes available, another group of babies will be assigned by chance to receive either the ALVAC vaccine plus the new vaccine or placebo. Babies will have to stay in the clinic for one hour after each vaccine shot and return to the clinic 48 hours after each shot to be checked for problems. Study visits are every two weeks for the first 14 weeks of life, then every six months until the baby is two years old. There are a total of 12 study visits and the study lasts two years.

Required:

MOTHERS

- HIV positive
- At least 37 weeks pregnant

BABIES

- Less than 72 hours old
- May be receiving antiretroviral therapy

Not allowed:

MOTHERS

- Use of any investigational drug during pregnancy
- Use of passive or active immunotherapy during pregnancy
- Positive hepatitis B antigen at study entry

BABIES

- Receipt of any investigational therapy
- Receipt of passive or active HIV-specific immunotherapy
- Documented or suspected serious bacterial infection or metabolic illness
- Infants being breastfed

Location:

Bay Area Perinatal AIDS Center (BAPAC)
Maureen Shannon, FNP / CNM
(415) 206-8919

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

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Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Maureen Shannon, FNP / CNM
(415) 206-8919

140. HIV Infection in Children: 141W94

Title:

PROA-B3004: A Phase III, Open-Label Trial to Evaluate the Safety, Antiviral Efficacy and Pharmacokinetics of 141W94 Plus Current Therapy in HIV-1 Infected Children

Type of treatment:

141W94: antiretroviral, protease inhibitor

Purpose:

To see if 141W94 is safe and effective when combined with other antiretroviral drugs in fighting HIV infection in children. To see how 141W94 is processed by childrens' bodies.

About the study:

All patients will receive 141W94 to take in addition to two nucleoside analog drugs, such as AZT, ddI, ddC, d4T and 3TC. There are no placebos in this study. 141W94 will also be available in liquid form for those children who cannot swallow capsules. Study visits are once a month and the study lasts about one year. The study will provide 141W94 but will not supply the nucleoside analog medications.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 400 copies/mL
- HIV positive
- Between 4 and 18 years old
- Children taking antiretroviral medications should be on stable (no changes) treatment for at least 28 days prior to study entry

Not allowed:

- Any current opportunistic infections
- Treatment with chemotherapy or radiation within four weeks prior to study entry
- Females who are pregnant
- Use of any NNRTIs, such as delavirdine, nevirapine or DMP 266 within 28 days of study entry

Location:

Children's Hospital Los Angeles
Sarah Fox-Wheeler, RN
(213) 669-4537

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

141. HIV Infection in Children: AZT, ddI, ddC, d4T, 3TC, Nevirapine, Ritonavir, Nelfinavir

Title:

Pediatric ACTG 366: A Phase I/II Master Protocol of Novel Antiretroviral Combination Therapies in Antiretroviral Experienced Children with Rapidly Progressing or Advanced HIV Disease (RAD)

Type of treatment:

d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Ritonavir: antiretroviral, protease inhibitor
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To see if certain drug combinations can decrease the amount of HIV in the blood and to see how long this decrease might last. To see if these combinations are safe to give to children with advanced HIV disease and to find the right doses of these drugs when used in various combinations.

About the study:

Patients will take one or two nucleoside analogs (such as AZT, ddI, ddC, d4T or 3TC). Depending on which drugs have previously been taken, children will also be assigned to take either **1)** nevirapine plus nelfinavir or nevirapine plus

ritonavir; **2)** nevirapine plus nelfinavir plus ritonavir or **3)** nelfinavir plus ritonavir. All study drugs are taken by mouth two or three times a day. Patients and doctors will know which medications they are taking and all medications are provided by the study. Study visits are once a month for the first six months, then every two months for the remainder of the study . The study lasts one year with the option to continue for an additional 48-week extension if children do well with their medications.

Required:

- Evidence of HIV infection
- Between 6 months and 21 years old
- Evidence of HIV disease progression or advanced disease while receiving at least eight weeks of unchanged continuous antiretroviral therapy
- Must be able to receive at least two drugs which patients have never used. One of these drugs must be ritonavir, nevirapine or nelfinavir

Not allowed:

- Acute treatment for a serious bacterial, viral or opportunistic infection within 14 days of study entry
- Cancers requiring chemotherapy
- Pregnant females
- Prior pancreatitis or severe peripheral neuropathy
- Prior use of ritonavir and nelfinavir in combination

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

142. HIV Infection in Children: CD4-IgG2

Title:

Pediatric ACTG 351: Phase I/II Trial of CD4-IgG2 in HIV-1 Infected Children

Type of treatment:

CD4-IgG2: viral blocker

Purpose:

To see if CD4-IgG2 is safe and to see what effect it has against the HIV virus in children. To see how CD4-IgG2 is processed by childrens' bodies.

About the study:

This study has two parts. Part 1 is a dose-escalating study. This means that the first group of children to enroll will receive the lowest dose of CD4-IgG2. If no bad side effects are seen, the next group of children will receive a higher dose and so forth until the fourth group of children get the higest dose of CD4-IgG2. CD4-IgG2 is given once by infusion into a vein. The infusion lasts about one hour and children will have to stay overnight in the hospital on the day they receive the infusion. There will be several blood draws on the day of the infusion. Study visits are on Days 1, 3, 7, 14 and 28 following the single infusion. There will be blood draws on these days. There will also be visits at 2, 3 and 4 months after the single infusion. Part 1 lasts four months. Children who enroll in Part 2 will receive infusions of CD4-IgG2 once a week for four weeks. The dose given will be established from Part 1. Children will have to stay overnight in the hospital each day the infusion is given. After the last infusion (week 3), blood will be drawn at 1, 2, 6, 24 hours, 7 days, and 14 days to see how much CD4-IgG2 is in the blood. Study visits will be at Weeks 7, 11, 15 and 19. Part 2 lasts five months.

Required:

- CD4 cell (T-cell) range:
  age 2-5 years: less than 500
  age 6-12 years: less than 200
- Viral load range **(Part 2 ONLY)**: at least 10,000 copies/mL
- HIV positive
- Between 2 and 12 years old
- Stable (no changes) antiretroviral therapy for at least three months prior to study entry

Not allowed:

- Active opportunistic infections
- Females who are pregnant
- Use of steroids or other immunosuppressive therapy
- Children receiving IVIG
- Children currently participating in a vaccine trial
- Any routine vaccination within 30 days of study entry

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

143. HIV Infection in Children: DMP 266, Nelfinavir

Title:

Pediatric ACTG 382: A Phase I/II, Open-Label, AUC-Controlled Study to Determine the Pharmacokinetics, Safety, Tolerability, and Antiviral Activity of DMP 266 in Combination with Nelfinavir in Children

Type of treatment:

DMP 266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To see if DMP 266 in combination with nelfinavir is safe and effective in treating HIV infection in children. To see which dose of nelfinavir is safest and best when combined with DMP 266. To compare the capsule form of DMP 266 with the liquid form.

About the study:

Two groups of children will participate in this study. All children will take DMP 266 and nelfinavir. Children in Group I will take DMP 266 in capsule form. Children in Group II will take DMP 266 in syrup form. The dose of each drug will be determined by the child's weight. Nelfinavir is either a powder or a tablet and taken by mouth. Children taking nelfinavir in powder form should mix it with milk or baby formula. Study visits are every two weeks for the first two months, then once a month. At Weeks 2, 6 and possibly 10, children will take their study drugs at the clinic and remain there for multiple blood tests throughout the day. The study lasts 48 weeks and children will have the option to continue DMP 266 at the end of the study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: detectable (more than 400 copies/mL)
- HIV positive
- Age: **Group I:** 16 years old or younger
  Group II: between 3 months and 8 years of age
- Must be taking one or more NRTI, such as AZT, ddI, ddC, 3TC or d4T

Not allowed:

- Prior use of any protease inhibitors or NNRTIs, such as delavirdine or nevirapine
- Use of any experimental drug within 30 days of study entry
- Hepatitis due to any cause
- Any cancer requiring systemic chemotherapy
- Active AIDS-defining opportunistic infections or disease
- Females who are pregnant
- More than two episodes of moderate to severe diarrhea or vomiting lasting more than four days within three months prior to study entry

Location:

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

New

144. HIV Infection in Children: Fortovase™, Nelfinavir

Title:

Pediatric ACTG 397: A Randomized Trial of Two Saquinavir-Containing Combination Treatment Regimens in Children with HIV Infection

Type of treatment:

Fortovase™: antiretroviral, protease inhibitor
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To see if Fortovase™ (soft gel saquinavir) is safe and effective when combined with other anti-HIV drugs **OR** combined with nelfinavir (Viracept®) and other anti-HIV drugs in HIV-infected children.

About the study:

Children are assigned by chance to receive Fortovase™ plus two other anti-HIV drugs **OR** to receive Fortovase™ plus nelfinavir plus one or two other anti-HIV drugs. Both patients and their doctors will know which medications they are taking. Fortovase™ is a capsule and must be swallowed whole. Nelfinavir is available in tablet or powder form. The other anti-HIV drugs are not provided as part of the study and should be obtained by prescription. Study visits are once a month for the first four months, then every two months for the rest of the study. The study lasts about one year.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: more than 10,000 copies/mL
- HIV positive
- Between 3 and 16 years old
- Ability and willingness to swallow capsules

Not allowed:

- Acute opportunistic infections requiring treatment at the time of study entry
- Any cancers requiring chemotherapy
- Prior use of saquinavir (Fortovase™, Invirase™) or nelfinavir (Viracept®)
- Pregnancy or breastfeeding
- More than two episodes of moderate to severe diarrhea or vomiting lasting more than four days within three months of study entry
- Current use of investigational drugs or immunomodulators, such as interferons or interleukins

Location:

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

145. HIV Infection in Children: Indinavir, 3TC, d4T

Title:

Pediatric ACTG 395: A Multicenter, Open-Labeled, 48-Week Study to Investigate the Safety, Pharmacokinetics and Efficacy of Indinavir in Combination With Stavudine and Lamivudine in Pediatric Patients With HIV Infection

Type of treatment:

d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if the combination of indinavir (Crixivan®) plus stavudine (d4T) plus lamivudine (3TC) is safe and effective in treating HIV infection and to see how these drugs are processed by childrens' bodies

About the study:

All patients will receive indinavir, d4T and 3TC to take; there are no placebos in this study. All medications are taken by mouth. Study visits are every two weeks of the first month, then once a month for five months, then once every two months for the rest of the study. This study lasts 48 weeks.

Required:

- CD4 cell (T-celi) range: not applicable
- Viral load range: not applicable
- HIV positive
- Between 3 and 15 years old and able to swallow capsules

Not allowed:

- Pregnancy or breastfeeding
- Prior use of any protease inhibitors
- Prior use of stavudine **AND** lamivudine. Patients must be naive to at least one of these two medications
- Active opportunistic infections and/or serious bacterial infections. Acute therapy for such must be completed at least 14 days prior to study entry
- Current hepatitis or pancreatitis due to any cause
- Severe recurrent or persistent diarrhea
- Use of investigational drugs, immunomodulators (such as interferons or interleukins), growth hormone, chemotherapy or radiation therapy within 14 days prior to study entry

Location:

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

146. HIV Infection in Children: Interleukin-2

Title:

Pediatric ACTG 299: Phase I/II Trial of Recombinant Interleukin-2 in Symptomatic Human Immunodeficiency Virus-Infected Children

Type of treatment:

Interleukin-2: immune modulator

Purpose:

To see if interleukin-2 is safe and effective for treating children who are HIV-infected. To find the highest dose of interleukin-2 that is safest for children to take.

About the study:

This is a dose escalating study. This means that the first children to enter the study will receive the lowest dose of interleukin-2. If this dose is tolerated with no bad side effects, the next group of patients will receive the next highest dose level and so forth until the highest dose that is tolerated with no bad side effects is found **(Part A)**. Once the maximum tolerated dose has been determined, additional children will be enrolled to receive that dose **(Part B)**. Interleukin-2 is given as an infusion into a vein. Children will receive a continuous infusion for five days in a row every eight weeks. This is called a cycle and children will complete three cycles. Those children who participated in Part A and did not receive the maximum tolerated dose of interleukin-2 will be eligible to participate in Part B to receive that dose. Parts A and B both last 44 weeks.

Required:

- CD4 cell (T-cell) range:
  age 3-5 years: 500 - 1000
  age 6-12 years: 200 - 500
- Viral load range: not applicable
- HIV positive
- Between 3 and 12 years old. Patients are eligible if they enter the study prior to their 13th birthday
- Patients must be receiving the best available antiretroviral therapy for at least one month and not more than 12 months prior to study entry
- Children must have symptomatic HIV infection

Not allowed:

- Any active opportunistic infection
- Any steroids or other immunosuppressive therapy
- Current polyclonal or monoclonal antibody therapy
- Current use of IVIG
- Females who are pregnant

Location:

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

147. HIV Infection in Children: d4T, 3TC, Nevirapine, Nelfinavir, Ritonavir

Title:

Pediatric ACTG 377: A Phase II Rolling Arm Master Protocol (PRAM) of Novel Antiretroviral Therapy in Stable, Experienced, HIV-Infected Children PRAM-2: A Phase I/II Randomized, Multicenter Protocol Comparing Four Antiretroviral Regimens Containing Combinations of Protease Inhibitors, NRTIs and an NNRTI

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see which one of four drug combinations does the best job of reducing HIV viral load in the blood of HIV-infected children. To see if these drugs are safe when given to children.

About the study:

All children will take d4T and are assigned by chance to one of four combinations: nevirapine + ritonavir; 3TC + nelfinavir; nevirapine + nelfinavir or 3TC + nevirapine + nelfinavir. Both patients and their doctors will know which combination of medicines they are receiving. All medications are pills and taken by mouth. Study visits are once a month and the study lasts about one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 4 months and 17 years old
- Must have been receiving stable (no changes) antiretroviral therapy for at least 4 months prior to study enrollment
- Females of childbearing potential must have a negative pregnancy test

Not allowed:

- Past or current use of any of the drugs being used in this study (d4T, 3TC, nelfinavir, nevirapine, ritonavir)
- Past use of any protease inhibitor
- Any active opportunistic infections and/or serious bacterial infections or cancers at the time of study entry
- Females who are pregnant

Location:

Children's Hospital Los Angeles
Sarah Fox-Wheeler, RN
(213) 669-4537

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
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UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

148. Bacterial Infection Prevention in Children & Adolescents: Atovaquone, Azithromycin, TMP-SMX

Title:

Pediatric ACTG 254: A Randomized, Phase II/III, Double Blind, Placebo Controlled, Two-armed Study of Micronized-Atovaquone and Azithromycin as Compared to Trimethoprim-Sulfamethoxazole in the Prevention of Serious Bacterial Infections When Used in Children Aged 3 Months to 18 Years with HIV Infection.

Type of treatment:

Trimethoprim-Sulfamethoxazole: antibacterial
Atovaquone: antibacterial
Azithromycin: antibacterial

Purpose:

To find out if taking the drugs atovaquone and azithromycin together is as good or better than taking Septra alone in preventing serious bacterial infections.

About the study:

Patients are assigned by chance to receive atovaquone and azithromycin and placebo or Septra and placebo. All drugs are taken by mouth. Neither the patients nor their doctors know which drugs they are taking until the study ends. The study lasts two years.

Required:

- CD4 cell (T-cell) range: not specified
- Between 3 months and 18 years old
- HIV positive
- At risk for developing PCP

Not allowed:

- Active PCP
- Past use of atovaquone or azithromycin
- Being treated for MAC, toxoplasmosis, tuberculosis, cryptosporidiosis or microsporidiosis
- Women who are pregnant or breastfeeding

Location:

Children's Hospital Los Angeles
Sarah Fox-Wheeler, RN
(213) 669-4537

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

149. Growth and Nutritional Status in Infants: Infant Formula

Title:

Pediatric ACTG 247: A Randomized, Double-Blind, Controlled Study of an Increased Caloric Density Infant Formula and its Effect on Growth and Nutritional Status in HIV-Infected Infants

Type of treatment:

Infant Formula: formula

Purpose:

To compare a higher calorie formula to a standard calorie formula and to see it's effect on improved growth in HIV-infected infants.

About the study:

Newborns of HIV-infected mothers are assigned by chance to receive a higher calorie formula or standard calorie formula. After eight weeks, infants with negative HIV-specific tests (presumed HIV-negative) will be assigned by chance to discontinue the study or to continue the study using the standard calorie formula. Those infants who are HIV positive will continue to take the formula to which they were assigned. Neither patients nor their doctors will know which formula they are taking until the study ends. All infants assigned to continue the study treatment beyond the eight week study visit will have study visits at Weeks 16, 28 and 52. At Week 28, study formula will be discontinued. Infants will start eating other foods when and as recommended by their doctors. The study lasts one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV-infected mother
- Infants must be less than or equal to two weeks old
- Infants must weigh at least 4 pounds

Not allowed:

- Infants with congenital conditions that may result in a high probability that the infant will not survive beyond the 28-week treatment period
- Infants taking drugs that alter growth such as Megace, corticosteroids or growth hormone
- Any metabolic disorder resulting in malabsorption
- Women who decide to breastfeed their infants

Location:

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

150. HIV Infection in Children and Adolescents: Observational

Title:

Pediatric ACTG 219: Pediatrics Late Outcomes Protocol

Type of treatment:

Observational: none

Purpose:

To learn about the long-term survival and quality of life of infants and children enrolled in ACTG studies. To learn more about the differences between HIV disease progression in HIV+ infants and children, and the effects of anti-HIV drugs in infants and children who are not HIV+.

About the study:

All patients get physical exams and blood tests on a regular basis. Information on health problems and quality of life are also collected. Patients will be in the study until their 21st birthday.

Required:

- CD4 cell (T-cell) range: not specified
- An infant, child or adolescent born to an HIV+ woman who was enrolled in an ACTG study while pregnant, **OR**
- HIV+ infant or child ever enrolled in an ACTG treatment study

Not allowed:

- Children enrolled only in ACTG 220 or other observational studies

Location:

Bay Area Perinatal AIDS Center (BAPAC)
Maureen Shannon, FNP / CNM
(415) 206-8919

Children's Hospital Los Angeles
Sarah Fox-Wheeler, RN
(213) 669-4537

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center
Maternal Child Program
Melissa Scanlon, RN
(323) 226-5095

UCLA Medical Center - Pediatrics
Zane O'Keefe
(310) 206-6369

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

Compassionate Use, Expanded Access and Treatment IND Programs

Any new drug must be approved by the Food and Drug Administration (FDA) before it can be prescribed by a physician. FDA approval is based on the results of clinical trials. Many months or even years of clinical trials and analysis of the results may be needed before approval can be granted. Such a long testing period is necessary in order to learn about the safety and effectiveness of the drug. But sometimes, even during fairly early phases of testing, a drug may appear to have benefits which outweigh the risks of taking it before it has been fully tested. This is especially true when people cannot take any of the approved drugs, when approved drugs do not work, or for conditions which have previously been untreatable. Compassionate Use, Expanded Access and Treatment IND are programs which allow patients limited access to promising experimental treatments before they have been given full approval by the FDA. They are developed jointly by the FDA and the pharmaceutical company that makes the drug.

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Abacavir (1592U89)	HIV Infection, dementia	Glaxo Wellcome Expanded Access	800-501-4672
Adefovir dipivoxil (PREVEON)	HIV Infection CD4 count <50	Gilead Sciences Expanded Access	800-445-3235
Albendazole	Microsporidiosis	SmithKline Beecham Compassionate Use Protocol	800-877-7074, x6454 (physician calls only)
AmBisome (liposomal Amphotericin-B)	Cryptococcal meningitis failed standard Ampho-B	NeXstar Pharmaceuticals Expanded Access Program Program	800-787-8268
AmBisome (liposomal Amphotericin B)	Invasive fungal infections - any age failed standars Ampho-B	NeXstar Pharmaceuticals Compassionate Use Program	800-787-8268
ddC (zalcitabine, HIVID)	HIV Infection (pediatric)	Hoffmann-LaRoche Open Label Program	800-285-4484
Mitoguazone dihydrochloride (MGBG)	Non-Hodgkin's Lymphoma refractory or relapsed	Ilex Oncology Compassionate Use Program	210-949-8200
Nevirapine (Viramune)	HIV Infection CD4 count $\leq$ 200/mm^3 Pediatrics only	Boehringer-Ingelheim	800-595-5494
Nitazoxanide (NTZ)	*Cryptosporidium*	Unimed Pharmaceuticals Compassionate Use Protocol	800-864-6330 ext 3032
Sparfloxacin (Cinarcid)	Multidrug resistant TB	Rhone-Poulenc Rorer Compassionate Use Protocol	800-727-6737
Spiramycin	Chronic diarrhea caused by *Cryptosporidium*	Rhone-Poulenc Rorer Compassionate Use Protocol	800-727-6737
Thalidomide (Synovir)	Wasting syndrome Apthous ulcers	Celgene Compassionate Use Protocol	888-423-5436

California AIDS Drug Assistance Program

The California AIDS Drug Assistance Program (ADAP) was established to provide drugs to individuals who otherwise could not afford them. Individuals are eligible for ADAP if they (1) have a **federal** adjusted gross income below $50,000 per year, (2) have a valid prescription from a California-licensed physician, and (3) the drugs they need are not covered by Medi-Cal or other third-party payer. An individual is subject to a co-payment if his/her annual **federal** adjusted gross income is between 400% of poverty level and $50,000. Individuals with an annual gross income below 400% of poverty level receive the drugs free of charge.

For more information about ADAP call the California Office of AIDS at **916-327-6784**. County and local offices in California are listed on the next page. Other States have similar programs.

California AIDS Drug Assistance Program - Covered Drugs

Drug Names	Used for
Acyclovir, Zovirax	antiviral, herpes treatment
Albendazole, Albenza	microsporidiosis
Amitriptyline, generic only	antidepressant
Amphotericin B, Fungizone	fungal infections
Amoxicillin, generic only	antibiotic
Atovaquone, Mepron	antibacterial, PCP treatment
Azithromycin, Zithromax	antibacterial, MAC infections
Bleomycin sulfate, Blenoxane	antineoplastic, chemotherapy
Bupropion, Wellbutrin (short-acting only)	antidepressant
Cephalexin, oral generic only	antibiotic
Cidofovir, Vistide	antiviral, CMV disease
Clarithromycin, Biaxin	antibacterial, MAC infections
Clindamycin, Cleocin	antibacterial, PCP/Toxoplasmosis
Clofazimine, Lamprene	antimycobacterial, MAC infections
Clotrimazole, Mycelex, Lotrimin	antifungal, candidiasis
Codeine phosphate, oral generic only	analgesic
Codeine phosphate/aspirin, oral generic only	analgesic
Codeine sulfate, oral generic only	analgesic
Cyclophosphamide, Cytoxan	antineoplastic, chemotherapy
Dapsone,, Avlosulfon	antibacterial, PCP treatment
Daunorubicin, liposomal, DaunoXome	antineoplastic, KS treatment
Delavirdine, Rescriptor	antiretroviral, NNRTI
Desipramine, generic only	antidepressant
Dexamethasone, Decadron, Hexadrol	corticosteroid
Dicloxacillin, oral generic only	antibiotic
Didanosine, ddI, Videx	antiretroviral, nucleoside analog
Diphenoxylate, Lomotil	antidiarrheal
Doxorubicin, Adriamycin	antineoplastic, chemotherapy
Doxycycline, oral generic only	antibiotic
Dronabinol, Marinol	appetite stimulant, wasting syndrome
Erythromycin ethylsuccinate, oral generic only	antibiotic
Erythropoietin, EPO, epoetin alpha, Procrit	red blood cell stimulator
Ethambutol, Myambutol	antimycobacterial, MAC infections
Fenoprofen calcium, oral generic only	analgesic
*Fentanyl, Duragesic	analgesic
Filgrastim, Neupogen, G-CSF	white blood cell stimulator
Fluconazole, Diflucan	antifungal, candidiasis/cryptococcus
Flucytosine, 5FC, Ancobon	antifungal, candidiasis/cryptococcus
Fluoxetine, Prozac	antidepressant
Foscarnet, Foscavir	antiviral, CMV disease
Ganciclovir, IV, Cytovene, Implant	antiviral, CMV disease
Hepatitis B vaccine, Recombivax HB, Energix-B	vaccine
Hydrocodone, oral generic only	analgesic
Hydroxyurea, Hydrea, Droxia	HIV Host Factor Inhibitor, chemotherapy
Ibuprofen, oral generic only	analgesic
Ibuprofen/hydrocodone, oral generic only	analgesic

California AIDS Drug Assistance Program - Covered Drugs

Drug Names	Used for
Indinavir, Crixivan	antiretroviral, protease inhibitor
Indomethacin, oral generic only	analgesic
Interferon, alpha, Intron-A, Roferon-A	KS treatment
Itraconazole, Sporanox	antifungal
Ketoconazole, Nizoral	antifungal, candidiasis
Ketoprofen, oral generic only	analgesic
Lamivudine, 3TC, Epivir	antiretroviral, nucleoside analog
Lamivudine/Zidovudine, Combivir	antiretroviral, nucleoside analog
Leucovorin, Wellcovorin, Folinic acid	white blood cell protector, PCP treatment
Levorphenol, oral generic only	analgesic
Loperamide, Imodium	antidiarrheal
Megestrol acetate, Megace	appetite stimulant, wasting syndrome
Methadone, oral generic only	analgesic
Methotrexate, MTX, Reumatrex	antineoplastic, chemotherapy
Metronidazole, oral generic only	amoebiasis
Minocycline, oral generic only	antibiotic
Morphine sulfate, oral generic only	analgesic
Naproxen, oral generic only	analgesic
*Nandrolone decanoate, Deca-Durabolin	anabolic steroid, wasting syndrome
*Nandrolone phenpropionate, Durabolin	anabolic steroid, wasting syndrome
Nefazodone, Serzone	antidepressant
Nelfinavir, Viracept	antiretroviral, protease inhibitor
Neomycin sulfate, oral generic only	antibiotic
Nevirapine, Viramune	antiretroviral, NNRTI
Nortriptyline, oral generic only	antidepressant
Nystatin, Mycostatin	antifungal, candidiasis
Opium, tincture of, Laudanum	anidiarrheal
*Oxandrolone, Oxandrin	anabolic steroid, wasting syndrome
Oxycodone, oral generic only	anal;gesic
Paclitaxel, Taxol	antineoplastic, KS treatment
Paromomycin, Humatin	antiparasitic, Amoebiasis/Cryptosporidiosis
Penicillin V potassium, oral generic only	antibiotic
Pentamidine, aerosolized, Nebupent, Pentaire, Aeropent	antiparasitic, PCP treatment
Pneumococcal vaccine, Pneumovax, Pnu-Imune	vaccine
Prednisone, Deltasone, Meticorten, Orasone	steroid, anti-inflamatory
Pyrimethamine, Daraprim	antibacterial, toxoplasmosis
Rifabutin, Mycobutin	antimycobacterial, MAC infections
Ritonavir, Norvir	antiretroviral, protease inhibitor
Saquinavir, Fortovase, Invirase	antiretroviral, protease inhibitor
Sertraline, Zoloft	antidepressant
Stavudine, d4T, Zerit	antiretroviral, nucleoside analog
Sulfadiazine, Microsulfon	antibacterial, toxoplasmosis
Sulindac, oral generic only	analgesic
*Testosterone cypionate, Depotest, Duratest	anabolic steroid, wasting syndrome
*Testosterone enanthate, Andro LA, Delastryl	anabolic steroid, wasting syndrome
*Testosterone porpionate, generic only	anabolic steroid, wasting syndrome
Tetracycline, oral generic only	antibiotic
Trazadone, generic only	antidepressant
Trimethoprim, Trimpex, Proloprim	antibacterial, PCP treatment
Trimethoprim-Sulfamethoxazole, Bactrim, TMP-SMX, Septra	antibacterial, PCP treatment
Trimetrexate glucuronate, NeuTrexin	antibacterial, PCP treatment
Valacyclovir, Valtrex	antiviral, herpes treatment
Vancomycin, oral generic only	antibiotic
Venlafaxine, Effexor	antidepressant
Vinblastine, Velban	antineoplastic, chemotherapy
Vincristine, Oncovin, Vincasar	antineoplastic, chemotherapy
Zalcitabine, ddC, HIVID	antiretroviral, nucleoside analog
Zidovudine, AZT, ZDV, Retrovir	antiretroviral, nucleoside analog

* Restricted

California AIDS Drug Assistance Program

County and Local Contacts for AIDS Drug Assistance Program in California

Alameda County Health Dept.
(510) 667-3937

City of Berkeley
(510) 644-6355

Butte County
(530) 891-4226

Contra Costa County
Bud Getty
(510) 313-6602

Del Norte County
(707) 464-3191

El Dorado County
(916) 573-3160

Fresno County
(209) 445-3434

Glenn County
(916) 934-6588

Humboldt County
(707) 268-2184

Imperial County
(760) 339-4448

Inyo County
(760) 872-4246

Kern County
(805) 861-0491

Kings County
(209) 584-1401, x4520

Lake County
(707) 263-2241

Lassen County
(530) 251-8183

Long Beach
Rosie Gutierrez
(562) 570-4316

Los Angeles County
(213) 351-8084

Madera County
(209) 675-7627

Marin County
(415) 499-3624

Mendocino County
(707) 463-4573

Merced County
(209) 385-7709

Modoc County
(530) 529-4400

Mono County
(760) 924-5415

Monterey County
(408) 772-7208

Napa County
(707) 253-4570

Nevada County
(916) 477-5551

Orange County
(714) 834-8175 or
(714) 834-8241

City of Pasadena
(626) 744-6029

Placer County
(530) 889-7144

Plumas County
(916) 283-6110

Riverside County
(909) 486-4626

Sacramento County
(916) 874-9583

San Benito County
(408) 636-4066

San Bernardino County
(909) 383-3036 or
(909) 386-8112

San Diego County
(619) 692-5545

San Francisco County
(415) 554-9168

San Joaquin County
(209) 468-3891

San Luis Obispo County
(805) 781-3660

San Mateo County
(650) 573-2188

Santa Barbara County
(805) 681-4758

Santa Clara County
(408) 299-6150

Santa Cruz County - Medi-Cruz Program
(408) 454-4574

Shasta County
(916) 247-3338

Siskiyou County
(916) 841-4062

Solano County
(707) 553-5124

Sonoma County
(707) 524-7402

Stanislaus County
(209) 558-4800

Tehama County
(530) 529-4400

Trinity County
(530) 623-1358

Tulare County
(209) 685-2535

Tuolumne County
(209) 533-7400, x7412

Ventura County
(805) 652-6152

Yolo County
(916) 666-8673

NOTE: The following counties do not provide ADAP services at the local level:

Alpine Colusa Mariposa Sutter Yuba

Please call the state Office of AIDS, ADAP

see page 87

Patient Assistance Programs

Some pharmaceutical companies have programs that provide free or lower cost medications to patients who could not otherwise pay for them. Each program has specific requirements about who is eligible and what kind of financial help is available. If you need help paying for any of the drugs listed below, talk to your doctor. He or she will need to call the coordinators of the appropriate program(s) and give them information about your financial status and prescription drug needs.

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Amplicor Viral Load Testing	HIV viral load	Roche Diagnostics	888-837-8727
Chiron bDNA Viral Load Testing	HIV viral load	Chiron Laboratories	888-448-5623
3TC (Lamivudine, Epivir)	HIV Infection	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Acyclovir (Zovirax)	Herpes simplex, Herpes zoster	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Alpha Interferon-2A recombinant (Roferon-A)	Kaposi's Sarcoma (>200 T-cells) anogenital neoplasms	Hoffmann-LaRoche, Inc. Oncoline (Reimbursement assistance and literature search) Indigent Patient Program	 800-443-6676 800-285-4484
Alpha Interferon-2B recombinant (Intron A)	Kaposi's Sarcoma anogenital neoplasms	Schering-Plough Corp. Commitment to Care	800-521-7157
Amphotericin B Lipid Complex (ABELCET)	Life threatening fungal infections	Liposome Co. Indigent Patient Program	800-335-5476
Amphotericin B oral suspension (Fungizone)	Fungal Infections	Bristol-Myers Squibb	800-272-4878
Atovaquone (Mepron)	PCP treatment	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
AZT (zidovudine, Retrovir)	HIV infection	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Azithromycin (Zithromax)	Toxoplasmosis, MAC	Pfizer Inc. Premiere Research	800-869-9979
Bleomycin (Blenoxane)	Chemotherapy	Bristol-Myers Squibb	800-272-4878
Cidofovir (Vistide)	CMV Retinitis	Gilead Sciences	800-445-3235
Cimetidine (Tagamet)	Ulcers	SmithKline Beecham, Access To Care	800-546-0420
Ciprofloxacin (Cipro)	Bacterial Infections	Bayer Indigent Patient Program	800-998-9180
Clarithromycin (Biaxin)	MAC	Abbott Laboratories Physician calls only	800-688-9118
Clindamycin (Cleocin)	PCP treatment	Upjohn Co. Patient Assistance Program	800-242-7014
Clofazimine (Lamprene)	MAC Treatment/Prevention	Novartis Pharmaceuticals Patient Assistance	800-257-3273
Combivir (AZT/3TC Fixed Dose)	HIV Infection	Glaxo Wellcome Co. HIV Patients Assistance Program	800-513-3028

Patient Assistance Programs

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Compazine (Prochlorperazine)	Nausea	SmithKline Beecham Access To Care	800-546-0420
Crixivan (Indinavir)	HIV Infection	Merck Pharmaceuticals	800-850-3430
DaunoXome (liposomal daunorubicin)	KS	NeXstar Pharmaceuticals	800-226-2056
Delavirdine (Rescriptor)	HIV Infection	Pharmacia-Upjohn	800-711-0807
ddC (zalcitabine, HIVID)	HIV infection	Hoffman-La Roche Patient Assistance Program	800-282-7780
ddI (didanosine, Videx)	HIV Infection	Bristol-Myers Squibb Videx Assistance Program	800-272-4878
d4T (stavudine, Zerit)	HIV Infection	Bristol-Myers Squibb Patient Assistance Program	800-272-4878
DOXIL (doxorubicin, liposomal)	Kaposi's Sarcoma	SEQUUS Pharmaceuticals Patient Assistance Program	800-375-1658
Dronabinol (Marinol)	Appetite stimulant	Roxane Laboratories Patient Assistance Program	800-274-8651
EPO (erythropoietin, Procrit)	AZT-related anemia	Ortho Biotech Procrit Financial Assistance Program	800-553-3851
Ethambutol (Myambutol)	TB treatment, MAC treatment	Wyeth-Ayerst Lederle Labs Patient Assistance	800-568-9938
Fluconazole (Diflucan)	Fungal infections	Pfizer Inc. Diflucan Patient Assistance program	800-869-9979
Foscarnet (Foscavir)	CMV disease, acyclovir-resistant HSV	Astra Pharmaceuticals Foscavir Assistance	800-488-3247
Fortovase (saquinavir)	HIV Infection	Hoffman-LaRoche Patient Assistance Program	800-282-7780
Ganciclovir (Cytovene)	CMV disease	Roche-Syntex Laboratories Provisional Assistance Programs	800-282-7780
Ganciclovir (oral)	CMV retinitis	Roche BioScience - physicians only	800-282-7780
Ganciclovir implant (Vitrasert)	CMV retinitis	Chiron Vision Patient Assistance Program	800-843-1137
G-CSF (Neupogen)	AZT-related neutropenia	Amgen, Inc.	800-272-9376
GM-CSF (Leukine)	AZT-related neutropenia	Immunex Corporation (Physician calls only)	800-334-6273
Human Growth Hormone rHGH Serostim	HIV Wasting Syndrome	Serono Laboratories	800-714-2437
Hydroxyurea (Hydrea)	HIV infection	Bristol-Myers Squibb	800-272-4878
Itraconazole (Sporanox)	Histoplasmosis, Fungal infections	Janssen Pharmaceutica Patient Assistance Program	800-652-6227

Patient Assistance Programs

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Ketoconazole (Nizoral)	Fungal infections	Janssen Pharmaceutica Patient Assistance Program	800-652-6227
Megestrol Acetate (Megace)	HIV-related Wasting	Bristol-Myers Squibb Patient Assistance Program	800-272-4878
Methotrexate (Rheumatrex)	Chemotherapy	Wyeth Ayerst Lederle Labs	800-568-9938
Mexiletine (Mexitil)	Peripheral Neuropathy	Boehringer Ingelheim	800-556-8317
Morphine Sulfate (Roxanol)	Pain Management	Roxane Laboratories	800-274-8651
Mycelex (Clotrimazole)	Oral Candidiasis (thrush)	Bayer Indigent Patient Program	800-998-9180
Nelfinavir (Viracept)	HIV Infection	Agouron Pharmaceuticals	888-777-6637
Nevirapine (Viramune)	HIV Infection	Roxane Laboratories Patient Assistance Program	800-274-8651
Nystatin (Mycostatin)	Oral Candidiasis (thrush)	Bristol-Myers Squibb	800-272-4878
Octreotide Acetate (Sandostatin)	Wasting	Novartis Indigent Patient Program	888-455-6655
Oxandrolone (Oxandrin)	Wasting	BTG Pharmaceuticals	800-741-2698
Paclitaxel (Taxol)	KS Chemotherapy	Bristol-Myers Squibb	800-272-4878
Paromomycin (Humatin)	Cryptosporidiosis	Parke-Davis Patient Asistance	908-725-1247
Pentamidine (Nebupent)	PCP Prophylaxis	Fujisawa, USA, Inc.	800-888-7704, x8607
Pentoxifylline (Trental)	HIV Infection, KS, Dementia	Hoechst Marion Roussel Inc. Indigent Patient Program	800-552-3656
Phenytoin (Dilantin)	Seizure disorder	Parke-Davis Patient Assistance	908-725-1247
Pyrimethamine (Daraprim)	Toxoplasmosis	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Pyrazinamide (USP)	TB Treatment	Wyeth Ayerst Lederle Labs	800-568-9938
Rifabutin (Mycobutin)	MAC	Pharmacia Upjohn Inc.	800-242-7014
Ritonavir (Norvir)	HIV Infection	Abbott Labs Temporary Assistance Program (Physicians only)	800-659-9050
Salk Vaccine (Remune)	HIV Infection	Immune Response Corp.	800-422-5448
Saquinavir (Invirase)	HIV Infection	Hoffman-LaRoche, Inc. Patient Assistance Program	800-282-7780
Streptomycin	TB Treatment	Pfizer, Inc. Patient Assistance Program	800-254-4445

Patient Assistance Programs

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Sustiva (efavirenz, DMP 266)	HIV Infection	DuPont Pharmaceuticals	800-334-4486
Testosterone (Testoderm patch)	Wasting	Alza Pharmaceuticals	800-321-3130 ext. 2287
TMP/SMX (Septra)	PCP prophylaxis and treatment	Glaxo-Wellcome HIV Patient Assistance Program	800-513-3028
TMP/SMX (Bactrim)	PCP prophylaxis and treatment	Hoffman-La Roche Inc., Patient Assistance	800-282-7780
Trimetrexate (Neutrexin)	PCP treatment	US Bioscience Patient Assistance	800-887-2467
Valacyclovir (Valtrex)	Herpes Treatment	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Vinblastine (Velban)	Chemotherapy	Eli Lilly Cares	800-545-6962
Vincristine (Oncovin)	Chemotherapy	Eli Lilly Cares	800-545-6962
WinRho SD	Thrombocytopenia	Univax Biologics	800-789-2099

Common Questions about Clinical Trials

What is a clinical trial?

A new drug goes through many tests in the lab before people take it. If the results are good, the drug is tested in small groups of people. When people take a new drug as part of a study, it is called a clinical trial.

The results of a clinical trial are very important. They tell us about the safety of the drug when people take it. They also tell us if the drug helps people get better.

Why should I join? What do I get out of this?

Here are some of the reasons to join a clinical trial:

- The treatment being tested may work for you.
- Clinical trials may be the only way to get a promising new drug.
- Drugs taken as part of a clinical trial are usually free. (Even if a drug you want to take is available on the "under ground," or by prescription, you may not be able to afford it).
- You can help speed the development of new treatments for HIV.

Will I be used as a "guinea pig"?

Before you join a clinical trial, you should understand what will happen during the study and what the researchers hope to learn. When you join a clinical trial, you volunteer of your own free will. Even though you signed a consent form, you have the right to quit at any time.

In most cases, you join a clinical trial because you already have a disease and you think the drug being tested may help you. Sometimes, you may join a clinical trial while you are still healthy, in the hope that the treatment may prevent you from getting sick.

What if the drug makes me sicker?

The researchers who design the trials always plan what to do if a volunteer gets ill from the drug they are studying. If the drug makes you sicker, you may have to take a lower dose, or stop taking the drug completely. In some trials, you might be switched to another drug. You should keep in close contact with your doctor as well as the researchers so they can treat any side effects as soon as possible.

Will I have to take a placebo ("sugar pill")?

Placebos are usually used only when no effective treatment is known. In these cases a "placebo-controlled" study is the only reliable way to find out if a drug works. Some patients are asked to take placebos so researchers can learn whether changes in health are caused by the drug, or would have happened without treatment.

Patients who take placebos get the same medical attention as people who get the study drug. Usually, all patients in the study are offered the active drug if it is shown to be safe and effective.

How can I tell which trial might be good for me?

The more you know about your own health status and about HIV disease, the easier it will be for you to make decisions about what trials may be good for you. You should always talk to your doctor or health care provider to get their opinions, too. We list contact names and numbers for the trials included in this directory so you or your doctor can get more information about trials you are interested in.

What are my rights as a patient?

The people involved in your care must treat you with consideration and respect. You have the right to:

- be told all the important details about your care
- ask questions and have them answered
- say no to any test, procedure or medication
- go to another health care provider to get more information
- know the names of anyone you talk to
- read your medical records with your health care provider
- make your own decisions about your health care
- know that your medical records will be kept confidential

What are my responsibilities as a patient?

The researchers have a right to expect certain things from you, too. As a patient, you have the responsibility to:

- be honest about your medical history and anything in your lifestyle which may affect your health
- follow instructions and take the study drug(s) as requested
- keep appointments or re-schedule them in advance
- report any changes in your health
- be sure you understand the facts before you make a complaint

What is informed consent?

Researchers are required by law to give you all the facts about a study before you join. This information must be explained in a way that you can understand. Before you join a study, you will be asked to read and sign a consent form. This is called giving ***informed consent***.

When you sign the consent form, it means that you have been given all the information about the study, and that you agree to join. The consent form is not a contract. You do not give up any rights if you sign the consent form. You can leave the study at any time.

What should I know before I sign the consent form?

Before you sign the consent form, you should know:

- the reasons for using the experimental treatment
- the risks and benefits of taking part in the study
- if there are any extra costs, doctor visits, lab tests, etc.
- what drugs you will have to take

Are there any other questions I should ask before I sign the consent form?

Before you decide to join a trial, you may want to know:

- How will information about me be handled to protect my privacy?
- Can I take the drug after the trial is over? Will I have to pay for it?
- If I get sick or develop health problems while on the trial, will I be taken off the trial?
- How can I find out the results of the trial?
- Are there other studies of this drug I should know about?
- Do I have to use birth control? If so, what kind? If I become pregnant will I have to leave the study?

What should I do if I don't understand something?

Do not sign the consent form until you understand everything in it. Keep asking questions. The staff should be able to answer most of them. However, there may not be enough information about certain drugs to answer some questions.

Why do some studies pay people to participate?

Some research studies pay people who volunteer to participate in them. Usually, studies only pay when there is no expected medical benefit to participants, such as when a new drug is being tested for only a short amount of time. Sometimes studies pay when they ask a lot of time and energy from participants, such as overnight stays in the hospital, or long surveys about personal issues.

Some researchers feel that the offer of money is not always ethical because it may tempt some people to take risks that they would not take otherwise. Ask and understand why the study is paying participants before you decide whether to join. Keep in mind that studies that pay usually do not pay until the study is over.

When studies do not pay, it is because the potential benefit of the study is felt to be enough compensation for the effort and risk of participating in it. If a study gives you free medication, check-ups, lab tests and helps you to be healthier by curing or preventing disease, then you *do* get something out of your participation.

Getting more information about specific studies

If you want to find out more about a specific clinical trial, call the person listed under "Location" for that trial. This is usually a research nurse or study coordinator. S/he will ask you some questions about your health to find out if you fit the entry criteria for the trial. It is a good idea to have a copy of your most recent laboratory tests, such as blood tests and T-cell counts, when you call.

Finding out if you're eligible: The screening visit

If the research nurse thinks you may be eligible, s/he will ask you to come in for a "screening" visit. At this visit, someone will explain the study to you, and you will give them more information about your health and your medical history. You may also have a brief physical exam and have some blood tests done.

Giving "informed consent"

If you meet all the entry criteria you will be asked to sign a consent form. When you sign the consent form it means that you have been given all the information about the study, and that you agree to participate.

The first study visit

After you have signed the consent form, you can join the study during a "baseline" visit—the first official visit of the study. A lot of information is collected during the baseline visit, so it may take longer than your regular office visit.

Followup visits

If you are taking a new drug, you will probably be asked to come back to the office for another visit in 1 - 2 weeks. This is to watch for any side effects of the drug that you may be experiencing. If everything seems to be all right, you will be asked to come back for regular followup visits. Frequency of visits may vary from daily to every few months, depending upon the study.

Keeping in touch

It is important to come to each study visit, and to let the researchers know how you are doing. It's also important to keep seeing your regular health care provider. Everyone is interested in protecting your health and safety when you are in a clinical trial, so it is important to stay in touch.

There are a number of misunderstandings about women and clinical trials. Here are the facts about some of the most common misunderstandings.

Can women with HIV join clinical trials?

Yes. Every clinical trial has requirements about who can join. If a woman meets these requirements, she can join. Most clinical trials are open to both women and men.

Women often don't get enough information about clinical trials and think that they cannot join simply because they are women.

Check the index of this Directory for studies that are open only to women, but remember that women may also join nearly all of the other studies listed.

Are there special rules about birth control and pregnancy?

Yes. In many studies, women must agree to use birth control if they have sex with men. Pregnant or nursing women usually can't join a trial of an untested drug because it is not known if the drug might harm the baby. However, there are now a few studies for pregnant women.

What happens if a woman becomes pregnant while in a trial?

A woman should know the rules about pregnancy before she joins a trial. Different trials have different rules about whether a woman can continue in the trial if she becomes pregnant.

Some women think they must have an abortion if they become pregnant while in a study. This is not true. Every woman always has the right to make her own decisions about pregnancy. No one can force you to have an abortion. However, if you choose to have the baby, it may affect your continued participation in the trial.

If you become pregnant, you may want to talk to the contact people for the studies for children listed in this guide (pages 74-86). These people are usually experts in pregnancy and women with HIV and can give you the most current information.

Services for women with HIV -- Los Angeles Area

There are too many programs and services for women in the Los Angeles area to list here. To receive a full listing, contact AIDS Project Los Angeles for a free copy of their guide to LA resources.

AIDS Project LA (213) 993-1459 (English)
(213) 993-1483 (Spanish)

Services for women with HIV -- San Diego Area

Being Alive has programs for women and children, including treatment education and advocacy.

San Diego: (619) 291-1400 or 1-800-606-2224

Services for women with HIV -- Northern California

WORLD (Women Organized to Respond to Life-Threatening Diseases). These women publish a newsletter with treatment information, and organize classes to teach themselves about HIV, including information on clinical trials. They can also offer referrals to services in the Bay Area.

You may contact WORLD at (510) 658-6930.

Check the Resources section on page 117 for more resources of interest to women.

Children and Clinical Trials

Most trials for adults do not allow children under the age of 13 to join. But there are clinical trials designed especially for children from birth to age 13 or older. Children's research is done by doctors and nurses who are experts on children's bodies and health.

Why are there trials for children only?

Children's bodies are different from adults' bodies, and HIV affects children differently than adults. For example, children get certain infections more frequently than adults, and never get some infections that adults get. It is important that your child see a doctor who knows about both HIV and children.

Because children's bodies are different from adults', a drug may work differently in children. Some drugs work very well in children and not at all in adults. A child usually needs a lower dose of a drug. Some drugs are too strong to give to children or have side effects that are worse for children than adults. Because of these differences, most researchers feel that it is better to test drugs separately in children.

Is it ethical to do research with children?

Some people think that it is never right to do research with children because children are too young to decide for themselves to take part in research. They feel it is not fair to put children at risk. Others feel that with AIDS and other life-threatening diseases that don't have a cure, the risk of the disease is greater than the risk of taking a drug that hasn't been thoroughly tested. Research may be the only chance to get certain drugs, and these drugs may be the only hope of getting better.

A child's parent or guardian must give written permission before a child can join a clinical trial. This permission is called ***"informed consent"***.

Where can I find out more about clinical trials for children with HIV?

This Guide lists trials for children at the end of the clinical trials section beginning on page 78.

You can call the contact people for the studies listed there—these people are usually medical experts on children with HIV and should be able to answer your questions.

What does "youth" mean?

People use the term "youth" differently. It can mean people from 13 to 18 years old, or 13 to 21 years old, or 13 to 26 years old. Other words used for youth are "adolescent" and "teen."

Why are youth treated differently in clinical trials?

Youth are different physically and emotionally from both children and adults. Healthcare and support programs for youth take these differences into account.

In which trials may youth participate?

Most clinical trials allow youth to join. Often people between ages 13 and 18 are eligible for both children's and adults' clinical trials. We list age restrictions for all the trials in this directory.

Do youth under 18 need permission to join a clinical trial?

Yes, minors (younger than 18 years old) need to get written permission from a parent or guardian to join a drug trial, even if they get medical care at a clinic without permission. There are people working to change the laws in this area, and they may be able to help you join a trial without your parents' permission in certain situations. See the "Common Questions" section of this Directory for an explanation of what it means to give ***"informed consent."***

Youth and Clinical Trials

Medical & Referral Services for Youth with HIV—Northern California

Bay Area Young Positives (BAY Positives)
Antigone Hodgkins, Executive Director
518 Waller Street
San Francisco, CA 94117
(415) 487-1616

BAY Positives is an education, support and advocacy organization by and for young people with HIV from the entire Bay Area.

Project AHEAD
Clark Moore, Director
1242 Market Street, 3rd Floor
San Francisco, CA 94102
(415) 487-5777
Project Ahead provides information to HIV+ youth and their providers about clinical trials.

Larkin Street Medical Clinic
1044 Larkin Street (at Sutter Street)
(415) 673-0911
Free medical and support services for homeless and runaway youth ages 12 to 23.

UCSF Teen Clinic
400 Parnassus, 2nd Floor, Room A270
(415) 476-8626 (Dave Knopf)
Full medical and support services.

San Francisco General Hospital
1001 Potrero Avenue (between 22nd and 23rd Streets)
Teen and Adolescent Clinic (under 18 years old)
(415) 206-8376

Kaiser Teenage Clinic
2350 Geary Boulevard, 1st Floor
(415) 202-2213
Medical and support services for youth who have Kaiser insurance or MediCal.

Medical & Referral Services for Youth with HIV—Southern California

Childrens Hospital LA
Risk Reduction Program
5000 Sunset Boulevard, 4th Floor, LA, CA 90027
(213)669-2390
Free health care and treatment ot young people with HIV between the ages of 12 and 24. Case management, psychosocial and nutritionsal education services also available.

High Risk Youth Program: (213) 669-2503
4650 Sunset Boulevard #2
Los Angeles, CA 90027
Medical services for homeless youth.
Department of Adolescent Medicine: (213) 660-2450
This department has several open or about to open studies designed especially for youth. Some of these are "natural history" studies that are trying to learn about young people with HIV and their situations and needs. Call and participate!

LA County USC Medical Center: 5P21 Clinic
1300 North Mission Rd., LA, CA 90033
(213) 343-8255
Adult, maternal and pediatric care and medical services.

Youth HIV Project
5000 Sunset Boulevard, 4th Floor, LA, 90027
(213) 669-2390
Free medical crae for HIV infected youth 12 to 20 years old, support groups, case management, health education.

Children's Hospital and Health Center
3020 Children's Way
San Diego, CA 92123
(619) 576-1700

Injection Drug Users and Clinical Trials

Injection drug users and people who use illegal street drugs, such as heroin, crack and speed, have often been left out of clinical trials. There are several reasons for this.

Street drugs can cause damage to the liver or kidneys. If your liver or kidneys are already damaged, taking a study drug might cause even more harm. Some trials have complicated rules that participants must follow. Researchers may think that if you use drugs you won't show up for your clinic visits, or won't take the study drugs as directed.

Most of the clinical trials in this directory ***do not*** exclude people just because they have used illegal drugs. If you are told you cannot join a clinical trial, ask the reason why. If you are (or were) an injection drug user, one of the following reasons may explain why you cannot join the trial.

Damaged liver or kidneys

Doctors can use certain laboratory tests to find out if your liver and kidneys are healthy. This is important, because you can have harmful side effects from the study drug if your liver or kidneys are damaged. These tests are usually done during the "screening" visit. If any of the tests are "outside normal limits," you may not be able to join the trial. This is done to protect your health.

Dangerous drug interactions

It can be very dangerous to mix some drugs, or to mix drugs and alcohol. Even mixing methadone with some study drugs can be dangerous. It is important to let your doctor and the researchers know ***every*** drug you are taking, to prevent harmful side effects.

Unable to comply with the "rules" of the study

Some trials have very complicated rules, and some people find it hard to follow them. That is why, if your doctor thinks you are "unreliable," you may not be able to join a clinical trial. If you do not take the study drug as directed, or frequently miss clinic appointments, it may be impossible to learn if the drug is working, or to prevent harmful side effects.

Clinical Trials Sites

AIDS Community Research Consortium
1048 El Camino Real, Suite A
Redwood City, CA 94063
(650) 364-6563

AIDS Healthcare Foundation
1300 N. Vermont Ave., Suite 502A
Los Angeles, CA 90027
(213) 913-3953

AIDS Oncology Practice at UCSF/Mt. Zion
2356 Sutter Street, 5th Floor Pavilion
San Francisco, CA 94115
(415) 567-5581

AIDS Research Alliance
621-A North San Vicente Blvd.
West Hollywood, CA 90069
(310) 358-2429

AltaMed HIV Services
5427 Whittier Blvd.
East Los Angeles, CA 90022
(323) 869-1900

Bay Area Perinatal AIDS Center (BAPAC)
1001 Potrero Avenue, Room 6D1
San Francisco, CA 94110
(415) 206-8919

California Partners Study
UCSF Dept. of OB/GYN
74 New Montgomery, Suite 400
San Francisco, CA 94105-3411
(800) 262-2430

Center for Special Immunology - Irvine
100 Pacifica, Suite 100
Irvine, CA 92718
(714) 753-0670

Children's Hospital Los Angeles
4650 Sunset Boulevard
Los Angeles, CA 90027
(213) 669-4537

Children's Hospital, Oakland
747 - 52nd Street
Oakland, CA 94609
(510) 428-3337

City of Hope National Medical Center
1500 E. Duarte Road
Duarte, CA 91010
(626) 301-8434

Community Consortium
(See page 115 for a list of participating sites and providers)
3180 18th Street, #201
San Francisco, CA 94110
(415) 476-9554

Community Eye Medical - Brian G. Terry, MD
301 S. Fair Oaks Avenue, #104
Pasadena, CA 91105
(818) 287-2000

East Bay AIDS Center
3031 Telegraph Avenue, Suite 235
Berkeley, CA 94705
(510) 204-1870

Harbor-UCLA Medical Center
1124 W. Carson Blvd.
REI N-24
Torrance, CA 90502
(310) 222-3848

HIVCare, Saint Francis Memorial Hospital
900 Hyde Street
San Francisco, CA 94109
(415) 353-6215

Institute for HIV Research and Treatment
California Pacific Medical Center - Davies Campus
Castro and Duboce Streets
San Francisco, CA 94114
(415) 565-6660

Kaiser Permanente - Los Angeles
1505 North Edgemont, 2nd Floor
Los Angeles, CA 90027
(213) 783-8172

Clinical Trials Sites

Kaiser San Francisco - HIV Research Unit
2590 Geary Boulevard
San Francisco, CA 94115
(415) 202-3480

Kaiser San Francisco - Opthalmology
1635 Divisadero Street, Suite 400
San Francisco, CA 94115
(415) 202-3980

Kraus Medical Partners
5901 W. Olympic Boulevard, Suite 310
Los Angeles, CA 90036
(213) 930-2324

LAC-USC Medical Center ACTU
1300 North Mission Rd.
Los Angeles, CA 90033
(323) 343-8288

LAC-USC Medical Center - Maternal Child Program
1640 Marengo Avenue
HRA Bldg., 3rd Floor
Los Angeles, CA 90033
(323) 226-5068

LAC-USC Medical Center - Norris Cancer Hospital
1441 Eastlake Ave., Room 3016 MS 34
Los Angeles, CA 90033
(323) 865-0371

Marcus Conant, MD Clinical Research
350 Parnassus Avenue, Suite 808
San Francisco, CA 94117
(415) 661-2613

Marin County Specialty Clinic
250 Bon Air Road
Greenbrae, CA 94904
(415) 499-7377

Pacific Oaks Research Group
8641 Wilshire Boulevard, Suite 305
Beverly Hills, CA 90211
(310) 360-8800

Quest Clinical Research, San Francisco
2300 Sutter Street, Suite 202
San Francisco, CA 94115
(415) 353-0800

Retina-Vitreous Group-David Boyer, MD
8641 Wilshire Blvd., Suite 210
Beverly Hills, CA 90211
(310) 854-6201

St. Luke Medical Group & Clinical Trials
1855 1st Avenue, Suite 300A
San Diego, CA 92101
(619) 235-4211

San Francisco General Hospital Dermatology
SFGH 4M70
San Francisco, CA 94110
(415) 206-8680

San Francisco General Hospital GI Clinic
1001 Potrero Avenue, Room 3C
San Francisco, CA 94110
(415) 206-8824

San Mateo County AIDS Program
3700 Edison Street
San Mateo, CA 94403
(415) 573-2588, 415-573-2385

Santa Clara Valley Medical Center
2400 Moorpark Avenue, Suite 316B
San Jose, CA 95128
(408) 885-4690

Sherman Oaks Hospital Research Institute
4911 Van Nuys Blvd., Suite 300
Sherman Oaks, CA 91403
(818) 205-1902

Stanford University Medical Center
Center for AIDS Research
300 Pasteur Drive, Room S-156
Stanford, CA 94305
(650) 723-6231

Tower Infectious Diseases
8631 West Third Street, Suite 1015E
Los Angeles, CA 90048
(310) 358-2300

UC Davis Cancer Center
4501 'X' St., G-126
Sacramento, CA 95817
(916) 734-3604

UC Davis Medical Center
Division of General Medicine
2221 Stockton Boulevard, Room 3107
Sacramento, CA 95817
(916) 734-7004

UC Irvine - Opthalmology
2000 Medical Plaza Drive, Suite 2004
Irvine, CA 92697
714-824-8303

UC Irvine Medical Center
101 City Drive South, Building 53
Route 81
Orange, CA 92668
(714) 456-7612

UCLA CARE Center
18033 Le Conte Avenue
BH-412 CHS
Los Angeles, CA 90095
(310) 206-6414

UCLA - Jules Stein Eye Institute
100 Stein Plaza, Room 3-110
Los Angeles, CA 90095-7000
(310) 794-5608

UCLA Medical Center - Pediatrics
10833 Le Conte Avenue
Los Angeles, CA 90095
(310) 206-6369

UCSD AIDS Malignancy Program
200 West Arbor Drive MC 8421
San Diego, CA 92103
(619) 543-2214

UCSD Treatment Center
2760 - 5th Avenue
San Diego, CA 92103-6325
(619) 543-8080

UCSD Mother, Child and Adolescent HIV Program
2760 - 5th Avenue
San Diego, CA 92103-6325
(619) 543-8080 ext. 261

UCSF AIDS Clinic
400 Parnassus Avenue, 5th Floor
San Francisco, CA 94143
(415) 476-3226

UCSF AIDS Program at SFGH / ACTU
995 Potrero Avenue, Building 80, Ward 84
San Francisco, CA 94110
(415) 476-9296, ext. 350

UCSF AIDS Program at SFGH/ICTG
635 Potrero Avenue
San Francisco, CA 94110
(415) 476-9296, ext. 330

UCSF Center for AIDS Prevention
Changes Project
74 New Montgomery Avenue, Suite 600
San Francisco, CA 94105
(415) 597-9165

UCSF Drug Research Center at SFGH
1001 Potrero Avenue, Building 100, Room 157
San Francisco, CA 94110
(415) 476-5906

UCSF Infectious Diseases Research
505 Parnassus Ave, Room AC30B
UCSF Box #0919
San Francisco, CA 94143
(415) 476-2308

UCSF Pediatric Immunology Program
505 Parnassus Avenue, Room M679
San Francisco, CA 94143
(415) 476-9373

UCSF/SFGH Dermatology
400 Parnassus, 3rd Floor
San Francisco, CA 94143
(415) 476-9219

UCSF/SFGH Endocrinology
1001 Potrero Avenue, Building 100, Room 321
San Francisco, CA 94110
(415) 206-4090

Veterans Administration Medical Center, San Francisco
4150 Clement Street, Room 111 W
San Francisco, CA 94121
(415) 750-6960

ViRx, Inc.
1375 Sutter St., Suite 407
San Francisco, CA 94109
(415) 353-5623

ViRx, Inc.-Palm Springs
1401 N. Palm Canyon Drive, Suite 202
Palm Springs, CA 92262
(760) 864-6266

Community Consortium Sites and Providers

The Community Consortium conducts clinical trials at over a dozen sites in the San Francisco Bay Area. Health care providers who are participating in the Consortium's clinical trials program are listed below. If you are interested in enrolling in a Consortium clinical trial and your health care provideris listed here, you can discuss enrollment during your next office visit.

San Francisco — Private Practices
Virginia Cafaro, MD
Jon Kaiser, MD
Martin Mass, MD
Kenneth Mills, MD
William Owen, MD
Carl Stein, PA

Castro-Mission Health Center — San Francisco
Nilda Alverio, MD
Jane Bailowitz, MD
Deborah Brown, MD
Toby Dyner, MD
Walter Krampf, MD
Lawrence Price, MD
Fred Strauss, MD

Mission Neighborhood Health Center — San Francisco
Colleen Foy, MD
Ricardo Alvarez, MD
Steve Leiner, NP
Richard Dolbec, MD

San Francisco General Hospital AIDS Outpatient Clinic (Ward 86)
Donald Abrams, MD
Gary Carr, NP
Peter Cohen, MD
Molly Cooke, MD
Steven Deeks, MD
Lisa Gooze, MD
Rick Hecht, MD
Sandra Hernandez, MD
Mark Jacobson, MD
Dennis James, PA
James Kahn, MD
Mary Lawrence-Hicks, NP
Jill Legg, MD
Catherine Lyons, NP

San Francisco General Hospital AIDS Outpatient Clinic (Ward 86), continued
J. B. Molaghan, NP
Edward Murphy, MD
Meg Newman, MD
Jenny Orland, MD
Herminia Palacio, MD
Michelle Roland, MD
Susan Shea, NP
John Stansell, MD
Jacqueline Tulskey, MD
Daniel Wlodarczyk, MD

San Francisco Dept. of Public Health — Youth Clinics
Pierre Marie-Rose, MD

Veterans Administration Hospital, San Francisco
Harry Lampiris, MD

East Bay — Private Practices
Robert Scott, MD

East Bay AIDS Center (Alta Bates Herrick Medical Center), Berkeley
Claire Borkert, MD
Steve O'Brien, MD
Susan Jacobson, MD
Jeffrey Burack, MD
Carol Brosgart, MD
Michael D'Arata, FNP

North Bay — Private Practice
Milton Estes, MD
Grace Dammann, MD
Debbie Jernberg, FNP

Access Project

1-800-734-7104
e-mail: AIDSTreatD@AOL.com
Internet:www.aidsinfonyc.org/network/access/index.html
A national clearinghouse for information about treatment access. For information about what drugs and treatments are available through federal, state or pharmaceutical-industry-sponsored programs, including:

- Medicaid and AIDS Drug Assistance Programs
- Patient Assistance /Expanded Access Programs
- Information about particular treatments.

AIDS/HIV Treatment Directory

Published twice a year by the American Foundation for AIDS Research, this directory is the most comprehensive source of information on approved and experimental treatments for HIV infections and other HIV-related disorders. Provides current information on clinical trial results, open protocols and enrollment, expanded access/ treatment IND programs, financial assistance programs, and additional resources for HIV/AIDS treatment. For subcription, contact AmFAR.
Phone: (800) 382-6327
Address: 120 Wall Street, 13th Floor
New York, NY 10002
Internet: http://txdir.amfar.org

AIDS Treatment News

Newsletter reporting on treatments for HIV / AIDS and public policy issues. Published twice a month. Subscription fee (available free or at low cost for people with limited income). Call for information. Highly respected.
Phone: (800) TREAT-1-2
(415) 255-0588
Address: P.O. Box 411256, San Francisco, CA 94141

AIDS Clinical Trials Information Service

Free national hotline, in English and Spanish, for information about AIDS Clinical Trials. Hours are Monday through Friday, 6:00am - 4:00pm (California time).
Phone: 1-800-874-2572 (1-800-TRIALS-A)

California AIDS Hotlines

(800) 367-2437
(800) 273-2437 - Niteline 5PM - 5AM PST

Gay Men's Health Crisis Treatment Issues

Reputable newsletter of experimental AIDS therapies published by Gay Men's Health Crisis in New York. Subscription charge.
GMHC Medical Information
129 West 20th Street
New York, NY 10011
Phone: (212) 807-6664
NY Hotline: (212) 807-6655
Internet: http://www.gmhc.org

Medical Alert

Newsletter of the National Association of People with AIDS
1413 K Street, NW
Washington, DC 20005

National HIV/AIDS Treatment Hotline

Treatment Information Service: (800) 448-0440
CDC National AIDS Hotline: (800) 342-2437

For federally approved treatment guidelines and information. Calls accepted from people with HIV, families, friends, health care providers. All calls are confidential.

Project Inform

Sponsors town meetings for information about and discussion of treatment twice a month. Information sheets and newsletter about available experimental drugs in treating AIDS, ARC, and HIV infection. Researches and disseminates information about where and how to obtain experimental drugs, current pricing, and what is known about dosage and clinical trials. California Hotline. Free, donations for information sheets and newsletters accepted. Knowledgeable staff.
Phone: (800) 822-7422 (national, toll-free)
(415) 558-9051 (San Francisco area)
Address: 205 - 13th St.#2001 San Francisco, CA 94103
Internet: http://www.projinf.org

Trials Search

A free computerized clinical trials matching service that provides people with HIV with personalized lists of studies for which they may qualify based on their medical history. Database covers all open trials in the United States. To receive a report, complete the Trials Search questionnaire (found in this Guide or by calling the number below), or conduct your own search at the Trials Search site on the World Wide Web. Trials Search is a service provided by the Community Consortium.

Phone: (800) 492-5777
(415) 476-5777
Fax: (415) 502-8686
Address: 3180 18th Street, #201, SF, CA 94110
Internet: http://hivinsite.ucsf.edu/tsearch

WORLD

(Women Organized to Respond to Life-Threatening Diseases)

Newsletter contains updates about clinical trials and treatment information of interest to women. Organization sponsors "HIV-University" (HIV-U) to teach women infected with HIV about all aspects of HIV disease.

Phone: (510) 658-6930
Address: 3948 Webster Street, Oakland, CA 94609

AIDS/HIV Treatment Information Resources on the World Wide Web

HIV InSite	http://hivinsite.ucsf.edu
The Body	http://www.thebody.com
Critical Path	http://www.critpath.org/
AEGIS	http://www.aegis.com/
AIDS Treatment News:	http://www.immunet.org/atn/
Intl. Assoc. of Physicians in AIDS Care:	http://www.iapac.org/
GMHC:	http://www.gmhc.org/
BETA:	http://www.sfaf.org/beta.html
Johns Hopkins	http://www.hopkins-aids.edu
Project Inform	http://www.projinf.org/
AIDS Treatment Data Network:	http://www.aidsnyc.org/network/index.html
Journal of the AMA (JAMA)	http://www.amaassn.org/special/hiv/
Harvard AIDS Institute Link Page	http://www.hsph.harvard.edu/

Northern California Treatment Education and Advocacy Resources

ACT-UP Golden Gate Chapter / Treatment Issues Committee
Political action group. Committee works to reform treatment and drug development priorities and revolutionize the health care delivery system. Many members are very HIV knowledgeable.
Phone: (415) 252-9200 Information & announcements
(415) 252-9275 Office
Address: 519 Castro Street SF, CA 94114

Asian Pacific Islander Wellness Center
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to Asian-American and Pacific Islander communities. English, Cantonese, Vietnamese, Mandarin, Tagalog and Khmer spoken.
Phone: (415) 292-3400
Address: 730 Polk Street, 4th Floor, SF, CA 94109

Bay Area Perinatal AIDS Center (BAPAC)
Center at San Francisco General Hospital that studies transmission of AIDS from pregnant women to their unborn children. Good source of information about women with HIV/AIDS and pregnancy.
Phone: (415) 206-8919
Address: 1001 Potrero Ave., Room 6D4, SF, CA 94110

New Village
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to African-American gay, bisexual and transgender communities.
Phone: (415) 356-8140
Address: 973 Market Street, #650 SF, CA 94103

Filipino Task Force on AIDS
Case management, client services, treatment advocacy, information, communication, and education on HIV/AIDS. Services targeted to the Filipino community. Tagalog/English speaking staff.
Phone: (415) 703-9880
Address: 1540 Market Street, #325, SF, CA 94102

Healing Alternatives Foundation
"Buyers Club" for products aimed at improving the health of HIV positive people and people with AIDS, including vitamins, minerals, herbals, nutritional supplements, experimental substances, foreign products and more. Good resource and information library to encourage client participation in their health care program. Library is free, Buyers Club costs $1.00 to join. Open 12:00 to 6:00 pm, Tuesday through Friday; 12:00 to 5:00pm Saturday.
Phone: (415) 626-4053
Address: 505 Castro Street, 2nd Floor, SF, CA 94114

Mission Neighborhood Health Center, La Clínica Esperanza
General medical care, clinical trials and social services for the Latino/a community. Bilingual (Spanish / English) staff.
Phone: (415) 431-3212
Address: 240 Shotwell Street, SF, CA 94110

Native American AIDS Project
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to American Indian community.
Phone: (415) 522-2460
Address: 1540 Market Street, #425, SF, CA 94102

Options Project, UCSF AIDS Program
Identifies individuals with primary HIV infection and provides those individuals with clinical care. Develops effective treatment programs for HIV infections of less then seven months duration and to see if current treatment plans are capable of eradicating HIV infection when given early in the course of disease. Provides ways of referring high risk individuals into behavioral intervention programs in order to prevent infection.
Phone: (415) 502-8100
Address: SFGH Bldg. 80, Ward 84, SF, CA 94110

Proyecto ContraSIDA por Vida
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to Latino communities, especially gay, lesbian, bisexual and transgender HIV positive people. Spanish and English spoken.
Phone: (415) 575-1642
Address: 2973 16th St., SF, CA 94110

San Francisco AIDS Foundation
Information and referrals to AIDS service organizations for people who need emotional or practical support. Spanish and Tagalog speaking staff. Publishes **BETA, the Bulletin of Experimental Treatments for AIDS**. **BETA** is published four times a year and has very up to date information on various aspects of HIV infection.
Phone: (415) 487-3000
Address: 10 United Nations Plaza, SF, CA 94102-6182

Los Angeles Area Treatment Education and Advocacy Resources

AIDS Project Long Beach
2017 E. 4th St.
Long Beach, CA 90814
(562) 434-4455

AIDS Project Los Angeles
1313 N. Vine St.
Los Angeles, CA 90028
(213) 993-1459
(213) 993-1483 (Spanish)
Publishes *HIV LA*, an extensive directory of HIV resources in LA and *Positive Living*, a monthly newsletter that includes timely treatment and clinical trial updates Call for free copies or subscriptions.

AIDS Service Center
1030 South Arroyo Parkway
Pasadena, CA 91105
(818) 441-8495

Asian Pacific AIDS Intervention Team
605 W. Olympic Blvd., Suite 610
Los Angeles, CA 90015
(213) 553-1871

AIDS Prevention Team
1219 S. La Brea Ave.
Los Angeles, CA 90019
(213) 964-7820

Bienestar Latino AIDS Project
1169 N. Vermont Ave.
Los Angeles, CA 90029
(213) 660-9680

L. A. Shanti
1616 N. La Brea Ave.
Hollywood, CA 90028
(213) 962-8197

WomensLink
401 Hillcrest Blvd., Unit B
Inglewood, CA 90301
(310) 313-5139

Laguna Beach Resources

The Laguna Beach Community Clinic
362 Third St.
Laguna Beach, CA 92651
(714) 494-0761

Selected San Diego Area Resources

Being Alive Center for Women and Children
3265 5th Avenue
San Diego, CA 92103
(619) 298-5099
Direct services, advocacy and education

Being Alive-San Diego
4070 Centre St.
San Diego, CA 92103
(619) 294-9988
Newsletter, support groups, counseling, housing

Hemophilia Association
P.O. Box 23099
San Diego, CA 92193
(619) 560-8373

San Diego County Department of Health and Human Services / Office of AIDS Coordination
P.O. Box 85222
Administrative Center, Room 208
San Diego, CA 92186
(619) 515-6699

San Diego Health Alliance, HIV/AIDS Office
234 North Magnolia Avenue
El Cajon, CA 92020
(619) 579-8373

UCSD Medical Center
AIDS Testing and Treatment Center
2760 Fifth Avenue, Suite 30
San Diego, CA 92103
(619) 543-8080

Selected Medical Abbreviations:

<: less than
>: greater than
≤: less than or equal to
≥: greater than or equal to
qd: daily
tid: three times a day
bid: twice a day
PO: by mouth
PRN: taken as needed
SQ: subcutaneous (injected under the skin)
IV: intravenous (injected in a vein)
IM: intramuscular (injected in a muscle)
mg.: milligrams
ml.: milliliters
mm.: millimeters

ACTG (AIDS Clinical Trials Group): a network of medical centers around the country in which federally funded clinical trials are conducted to test the safety and effectiveness of experimental treatments for HIV infection and its complications. ACTG studies are sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), a branch of the National Institutes of Health (NIH).

Adjuvant: any substance that enhances the immune-stimulating properties of an antigen or the pharmacologic effect of a drug

Adverse reaction ("side effect"): toxic reaction to a substance. Common adverse reactions include rash, headaches, nausea, vomiting and drowsiness; and can be as severe as anemia, seizures and liver or kidney failure.

AIDS (Acquired Immunodeficiency Syndrome): the late stage of the illness triggered by infection with human immunodeficiency virus (HIV). According to the official definition published by the CDC, a person receives an AIDS diagnosis when he or she has a CD4 (helper T-cell) countof less than 200 and/or certain opportunistic infections common with advanced immune deficiency

AIDS-Defining Illness: one of the serious illnesses that occurs in HIV-positive individuals and a reason for an AIDS diagnosis according to the CDC's definition of AIDS. Among these conditions are PCP, MAC, AIDS dementia complex, AIDS wasting syndrome, invasive cervical cancer, Kaposi's sarcoma and CMV retinitis

AIDS Dementia Complex (ADC): a degenerative neurological condition, generally attributed to HIV disease, with a wide variety of clinical presentations including loss of coordination, mood swings and loss of inhibitions, and widespread cognitive deficit.

Anabolic steroid: a synthetic steroid used to increase muscle mass and weight. Anabolic steroids are versions of the natural hormone testosterone but have fewer masculinizing effects

Anaphylactic Shock: a life-threatening allergic reaction characterized by a swelling of body tissues (including the throat) and a sudden decline in blood pressure

Anemia: the incapacity of blood to transport enough oxygen to the body's tissues. Anemia may be caused by abnormally low number of red blood cells or insufficient or defective hemoglobin, the protein that carries oxygen in red blood cells. It is a condition that is often caused by AZT as well as by other drugs and illnesses that suppress the red blood cell production in bone marrow.

Anorexia: a lack or loss of appetite that leads to significant decline in weight

Antibacterial: a substance which stops the growth of bacteria.

Antibiotic: a substance which kills or inhibits the growth of disease causing organisms, such as bacteria and fungi. For example, penicillin for some bacteria, amphotericin B or nystatin for some fungi.

Antibody: a protein produced by plasma cells in response to a specific antigen. Antibodies bind to antigens, often resulting in the inactivation of the antigen itself or the organism to which the antigen is attached. *See also* Antigen.

Antifungal: a substance which kills or inhibits the growth of a fungus.

Antigen: a substance, especially a protein, which stimulates production of antibodies.

Antiretroviral: a substance that stops or suppresses the activity of a retrovirus (for example, AZT, ddI, ddC). HIV is a retrovirus. There are now antiretroviral drugs that suppress HIV in different ways, such as protease inhibitors and reverse transcriptase inhibitors.

Glossary

Antisense Drug: antisense drugs are designed to block viral genetic instructions, marking them for destruction by cellular enzymes, in order to prevent the building of new virus or the infection of new cells

Antiviral: a substance that stops or suppresses the activity of a virus (for example, acyclovir, ganciclovir, foscarnet).

Aphthous Ulcer: a painful oral or esophageal sore of unknown cause that has a deep eroded base. Aphthous ulcers are common in people with HIV and are treated with corticosteroids or thalidomide.

Asymptomatic: infection without symptoms. Someone may have HIV disease without showing any symptoms.

AZT intolerant: someone who has severe side effects from taking AZT and cannot continue taking it.

Baseline: the initial time point in a clinical trial or treatment regimen, just before someone starts to receive the treatment in question.

bDNA assay: see Viral Load

Bioavailability: the extent to which an oral medication is absorbed in the digestive tract and reaches the blood stream.

Biopsy: removal of a small amount of tissue from the patient, either surgically or with a small needle, for microscopic examination to determine if disease is present.

Blinding: in research, refers to the process of preventing patients and/or their doctors from knowing whether the patient is taking active drug or placebo. *See also Double-blind.*

Bone marrow: soft tissue in the interior of a bone where blood cells are produced.

Bronchoscopy: examination of the bronchi (lung passages) with the aid of a bronchoscope (a tube inserted into the lungs).

Buyers' Club: a nonprofit group that imports AIDS-related therapies available in other countries but not yet approved by the FDA for use in the United States.

Candida: a white, patchy fungus which often grows in the mouth or esophagus of people with AIDS, causing pain or difficulty in swallowing. Infection with *Candida* is known as "candidiasis" or "thrush."

CD4 cell: *see* T-cell

Center for Disease Control and Prevention (CDC): the federal public health agency serving as the center for preventing, tracking controlling and investigating the epidemiology of AIDS and other diseases.

Central nervous system (CNS): the brain and spinal cord.

Cerebrospinal Fluid (CSF): fluid that bathes the brain and the spinal cord. A sample of this fluid is often removed from the body for diagnostic purposes by a lumbar puncture (spinal tap).

Cervical Dysplasia: the development of abnormal tissue on the cervix, the outlet of the uterus, may progress to cancer.

Chemotherapy: the treatment of disease by chemical agents; usually refers to cancer treatment.

Clinical trial: a study which tests experimental medicines in human beings to see if it is safe and effective.

CMV: (abbreviation) *see* Cytomegalovirus.

Combination therapy (for AIDS): the use of two or more antiretroviral treatments in combination against HIV. *See also HAART.*

Community-Based Clinical Trial (CBCT): a clinical trial conducted primarily by primary-care physicians, rather than in academic research facilities

Compassionate use: an FDA program that makes certain experimental drugs available to seriously ill people when no other treatment exists or when the patient cannot tolerate other treatments.

Controlled Trial: a clinical study in which one group of participants receives an experimental drug while another group receives either a placebo or an approved standard therapy.

CPCRA (Community Programs for Clinical Research on AIDS): a branch of the NIH's Division of AIDS that supports clinical trials based on local networks of practicing physicians.

Cryptococcal meningitis: a fungal infection caused by *Cryptococcus neoformans* that affects the three membranes (meninges) surrounding the brain and spinal cord. Symptoms include severe headache, dizziness, nausea, loss of appetite, vision disorders and mental deterioration.

Cryptosporidiosis: an opportunistic infection of the intestines caused by a protozoan parasite (*Cryptosporidium parvum*)

Cytomegalovirus (CMV): a virus that can cause aching, fever, mild sore throat, fatigue and enlarged lymph nodes. In AIDS, severe CMV infections can produce hepatitis, pneumonia, retinitis and colitis, leading in some cases to blindness, chronic diarrhea and death.

Data and Safety Monitoring Board (DSMB): an independent panel of clinical research experts responsible for the ongoing review and, when necessary, modification or termination of a clinical trial to insure the safety of participants.

Desensitization: gradually increasing the dose of a medicine in order to overcome severe allergic reactions.

Diagnosis: determining the cause and nature of an illness

Disseminated: spread throughout the body.

Dose-ranging or dose-escalating: describes a preliminary clinical trial in which the amount of a drug is either periodically increased or increased with each new trial arm that is added. Used to determine how well a drug is tolerated and what its optimum dose might be.

Double-blind (double-masked): trial procedure in which neither experimental subjects nor doctors know which subjects are receiving the test drug and which are receiving a placebo or other therapy. This method is believed to promote faster and more objective results, as doctors' and patients' opinions about a test drug's efficacy might otherwise bias test results.

Dysplasia: abnormal changes or growth of cells and tissues.

Efficacy: a drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed.

Encephalitis: inflammation of the brain.

Endoscopy: viewing the inside of a body cavity with a device using flexible fiber optics.

Epstein-Barr Virus (EBV): a herpes-like virus that causes one of the two kinds of mononucleosis. EBV lies dormant in the lymph glands and has been associated with Burkitt's lymphoma and oral hairy leukoplakia.

Expanded access: (also called "parallel track") a procedure established by the FDA which permits the use of investigational drugs by individual physicians. The purpose of this program is to make the drug available to patients who need it, while collecting at least some limited data on efficacy and toxicity.

Experimental drug: a drug that is being tested for use as a treatment for a specific condition in a specific population.

FDA, Food and Drug Administration: The U.S. government department that approves and regulates drugs and medical devices. Pharmaceutical companies must have FDA approval to sell a new medicine.

Fungal Infection: a range of distinct diseases caused by fungi. Candidiasis, cryptococcosis and histoplasmosis are examples of AIDS-related fungal infections.

Gene Therapy: any of a number of experimental treatments in which cell genes are altered or added to. As it concerns HIV, gene therapies attempt to provoke new immune activity or try to make cells resistant to infection.

Genotypic Testing: an experimental blood test that determines the genetic sequences of an organism. In HIV, frequently performed in order to establish whether certain mutations housing drug resistance are present.

HAART (Highly Active Antiretroviral Therapy): aggressive anti-HIV treatment usually including a combination of protease and reverse transcriptase inhibitors whose purpose is to reduce viral load to undetectable levels.

Herpes: 1) a group of viruses including herpes simplex I (HSV I), herpes simplex II (HSV II), varicella zoster (also called shingles), Epstein-Barr virus, and cytomegalovirus. 2) a common name for blisters on the mouth or genital regions caused by herpes simplex I and II.

Histoplasmosis: a fungal disease resulting from infection with *Histoplasma capsulatum*

HIV: (abbreviation) *see* Human Immunodeficiency Virus.

HIV positive: having antibodies to the human immunodeficiency virus in the body. Implies infection with HIV.

HIV RNA tests: see "Viral Load"

Hodgkin's Disease: a progressive malignant cancer of the lymphatic system.

Human Immunodeficiency Virus: a slow-acting retrovirus which many people believe to be the sole or foremost causative agent of AIDS .

Immune Thrombocytopenic Purpura (ITP): an autoimmune disease, in which the destruction of platelets (thrombocytes) leads to an increased susceptibility to bruising and bleeding.

Immunomodulator: a drug which alters, suppresses or strengthens the immune system, such as interleukins and interferons.

IND: (abbreviation) *see* Investigational New Drug.

Induction: the initiation of a particular therapy

Informed Consent: the ability of people receiving experimental therapies to make competent decisions about their medical care.

Infusion: the process of giving a substance (medication, food supplements, etc.) to a patient by injecting it into the blood stream. This procedure can either be a one-time event or continued over many hours, days or months.

Institutional Review Board (IRB): a regulating committee composed of internal staff, hospital affiliates and community members which review and approve all human trials conducted within a particular hospital or research center, ensuring that the trial is conducted in an ethical manner.

Investigational New Drug (IND): an application submitted to the Food and Drug Administration for permission to test a new drug or an old drug for a new indication in humans

ITP: *see* Immune Thrombocytopenic Purpura.

Kaposi's sarcoma (KS): an abnormal proliferation of small, poorly formed blood vessels which occurs in some people with AIDS. KS lesions may first appear anywhere on the body or in the soft palate of the mouth; they may also remain hidden in the internal organs.

Lesion: a change in tissue caused by disease. A point or localized patch of a skin disease. Other words similar to lesion include "sore" or "spot."

Leukocyte: any of the various white blood cells, which together make up the immune system.

Long-Term Nonprogressor: an individual who has been infected with HIV for at least seven to twelve years and yet retains a CD4 cell count within the normal range and no evidence of disease progression.

Long-Term Survivor: a looser term than long-term nonprogressor that indicates any person with any stage of HIV infection, including AIDS, who is stable over a period of years.

Lumbar puncture (LP): insertion of a needle into the spinal column to remove spinal fluid. Also called a spinal tap.

Lymphadenopathy: swollen, firm and possibly tender lymph glands. Causes may range from a temporary infection (such as the flu) to lymphoma.

Lymphoma: a malignancy (cancer) of lymphocytes, the cells that are responsible for normal immune function.

MAC (also called MAI): (abbreviation) *see Mycobacterium avium-Intracellulare* Complex.

Maintenance therapy: use of a treatment to maintain a desired effect that has already been achieved.

Malabsorption syndrome: decreased intestinal absorption resulting in loss of appetite, muscle pain, weight loss and diarrhea.

Malignant: used to describe cells or tumors growing in an uncontrolled fashion, either spreading to other sites through the blood stream or invading nearby, normal tissues. By definition, cancers are always malignant, and the term "malignancy" implies a cancer.

Microsporidiosis: an intestinal infection that causes diarrhea and wasting in people with HIV. It results from two different species of microsporidia, a protozoal parasite. Possible treatments are thalidomide and albendazole.

Molluscum Contagiosum: a skin condition caused by a pox infection, distinguished by small dome-shaped bumps on the face, upper trunk or extremities.

Monoclonal antibodies: custom-made immune system pieces that are used against one specific disease-causing agent

Mycobacterium avium-Intracellulare Complex (MAC): in people with AIDS, an infection which begins in the gut or lungs and is similar to tuberculosis. Later, the infection often spreads to other organs by way of the blood stream.

Naive: patients who haven't yet started a drug (regimen) for an infection or disease.

NCI (National Cancer Institute): a branch of the NIH that oversees considerable research in HIV and AIDS-related malignancies.

Neoplasm: tissue that grows more rapidly than normal; a tumor or growth. A neoplasm that does not spread to other tissues is described as benign. A neoplasm that spreads (metastasizes) to other tissues is termed malignant, and is commonly called cancer.

Neurological disorders: disorders of the central nervous system (brain and spinal cord), such as seizures or dementia, or of the peripheral nervous system (nerves) such as a neuropathy.

Neuropathy: see Peripheral Neuropathy

NIAID (National Institute of Allergy and Infectious Diseases): the federal agency that is responsible for a great deal of the government-sponsored AIDS research. NIAID is a branch of the NIH

NIH (National Institute of Health): the federal agency responsible for overseeing government-sponsored biomedical research. It is divided into 24 institutes and research centers.

Nuceloside Analog: a type of antiviral drug, such as AZT, ddI, ddC, 3TC or d4T.

OI: (abbreviation) *see* Opportunistic infection.

Open label trial: (also called non-masked or non-randomized trial) a drug trial in which both doctors and subjects know what drug a subject is taking (and at what dose).

Opportunistic infection (OI): illness which would not normally occur in someone whose immune system is functioning properly.

Oral Hairy Leukoplakia (OHL): a whitish lesion that appears on the side of the tongue and inside cheeks. The lesion appears raised, with a "ribbed" or hairy surface and may be caused by the Epstein-Barr virus

p24 antibody test: a test that measures the amount of antibodies in the blood against the p24 antigen.

p24 antigen test: a test that detects a protein fragment (p24) from HIV's core in blood and other body fluids. Not an accurate measurement of viral activity.

Pancreatitis: inflammation of the pancreas which can result in severe abdominal pain. Pancreatitis can be a side effect of a drug, but can occur due to including gallstones, viral infection and excessive alcohol intake.

Pap Smear: a microscopic examination of the surface cells of the cervix to detect tissue changes that could be forerunners of cervical cancer.

Parenteral: not through the mouth. Intravenous, intramuscular, and intradermal routes of administration of drugs are all parenteral

PCP: (abbreviation) *see Pneumocystis carinii* Pneumonia.

PCR (Polymerase Chain Reaction) Test: a very sensitive test to measure the amount of RNA or DNA (genetic material) of a virus or other organism in the blood or tissue. PCR tests are used to test HIV viral load.

Peripheral Neuropathy (PN): nerve damage characterized by sensory loss, pain, muscle weakness and wasting of muscle in the hands or legs and feet. It may start with burning or tingling sensations or numbness in the toes and fingers. PN may arise from an HIV-related condition or be the side effect of certain drugs.

Pharmacokinetics: the study of how drugs are absorbed, processed and eliminated by the body. This helps in determining the best route of administration, dosage and dosing schedule.

Phase I clinical trials: toxicity and dose-finding clinical studies which evaluate the drug's actions in the body, its safe dosage range, how it is absorbed, distributed, metabolized and excreted from the body. These trials are usually completed within a year and involve a small number of research subjects.

Phase II clinical trials: efficacy studies which often include several hundred human volunteers. They are designed to assess the drug's effectiveness precisely and to detect major adverse reactions (side effects).

Phase III clinical trials: involve up to several thousand participants to confirm earlier findings of effectiveness and to find side effects that occur only rarely or after a long period of treatment. They may last several years.

Phase IV clinical trials: studies designed to evaluate the long-term safety and effectiveness of a drug usually carried out after licensure of the drug. Also known as "Post-Marketing" studies

Phenotypic Testing: a test that measures some aspect of an organism's functions. For example, the amount of a certain drug needed to inhibit the growth of an HIV isolate in a test tube culture. If HIV has developed resistance to a certain drug, higher than normally administered amounts of that drug will be necessary to inhibit viral activity. Resistance is characterized as high-level, intermediate or low-level.

Placebo: an inactive substance against which test drugs (active or "real" drugs) are compared. In placebo-controlled trials the control group takes a placebo, while the test group takes an experimental drug. Many such studies are double-blinded so that neither the patients nor their doctors know which substance the patients are receiving. Placebos are usually harmless.

Platelets (also called thrombocytes): blood cells which help the normal clotting of blood.

***Pneumocystis carinii* Pneumonia (PCP):** a type of pneumonia caused by a common parasite that grows rapidly in the lungs of people with AIDS. PCP is the leading cause of death in AIDS. Rarely, *Pneumocystis carinii* infections may occur elsewhere in the body.

Prodrug: a class of drug which works after being converted in the body by metabolic processes

Prophylaxis: treatment intended to prevent people from getting a disease. For example, aerosolized pentamidine and Septra® have been shown to be effective for prophylaxis against PCP.

Protease Inhibitor: an antiretroviral drug that prevents HIV from making copies of itself (replicating) by blocking an enzyme called "protease".

Protocol: detailed plan which states a clinical trial's rationale, goal, hypothesis, the drugs involved, dosage levels, methods of administration and treatment durations, as well as who may participate, their disease and its severity.

Randomized trial: in a randomized trial, participants are assigned by chance to receive one of the treatments being studied.

Rebounding: a rapid increase in the viral load of HIV positive patients

Rechallenge: to take a drug again despite previous bad side effects.

Refractory: disease that is resistant to treatment.

Regimen: any particular treatment plan specifying which drugs are used, in what dose, according to what schedule, and for how long

Remission: when the symptoms of a condition disappear. "Remission" is not the same as "cure," because a disease can sometimes come back after it has been in remission.

Renal disease: disease of the kidney.

Resistance: reduction in sensitivity to a particular drug.

Retinitis: inflammation of the retina, a part of the eye. In people with AIDS, retinitis is often caused by CMV or HSV infections. If left untreated, it leads in most cases to blindness.

Ribozyme: recombinant RNA/enzyme combination designed to fit onto and split specific viral or cancerous genetic sequences from a cell's DNA. The gene for an anti-HIV ribozyme may be inserted into a cell to protect it from the virus's activity.

Salvage therapy: treatment for patients who are non-responsive to or cannot tolerate other available treatments for a particular condition.

Shingles: see Varicella Zoster virus

Side effects: any reaction that results from a drug or therapy. The term usually refers to a negative event, such as nausea, blood disorders or neuropathy.

Spinal tap: *see* Lumbar puncture.

STD: sexually transmitted disease.

Stem cell: one of the immature cells that are the source of all blood cells. Stems cells inhabit the bone marrow where they begin their differentiation and maturation process.

Study: a general term for any of a variety of research activities involving the collection, analysis or interpretation of data.

Symptom: any condition occurring because of a disease. For example, coughing is one symptom of *Pneumocystis* pneumonia, and headaches are a symptom of cryptococcal meningitis.

Systemic: throughout the body. Sometimes applies to medications that are taken orally or parenterally that saturate the entire body

T-cells (CD4 cells): also called T4 cells or T-helper cells. The T4 cell enhances the immune response to an infection through a complex series of interactions with other types of cells.

Thrush: a *Candida* infection of the mouth and throat often found in people with HIV infection.

Toxicity: the harmful side effects of a given drug.

Toxoplasmosis ("toxo"): a disease caused by a parasite, *Toxoplasma gondii*, often involving the brain, eyes, heart, liver and lungs.

TPN (Total Parenteral Nutrition): a liquid food substitute infused directly into a vein and designed to meet a person's entire nutritional needs.

Treatment-Naive: refers to patients with no history of previous treatment for a particular condition.

Vaccine: a substance that contains all or a portion of a disease-causing organism (usually "killed" by heat or chemicals) given for prevention or treatment of a disease. By stimulating production of antibodies, the vaccine helps to protect against infection by that organism.

Varicella Zoster Virus: a herpes virus that causes chicken pox in children. Its reactivation in adults causes shingles.

Viral Load: the number of viral particles (usually HIV) measured in a sample of blood plasma. Viral load test results are given as number of HIV copies or equivalents (Eq) per milliliter. There are two tests to measure viral load: PCR and bDNA.

Virus: microscopic agent which requires a living cell in order to reproduce. When viruses infect cells they can cause disease, often killing the cells they infect. Important viruses include Human immunodeficiency virus (HIV), Herpes and Cytomegalovirus (CMV).

Wasting Syndrome: progressive, involuntary weight loss associated with advanced HIV infection.

White Blood Cells: part of the immune system that protects the body against foreign substances such as disease-producing microorganisms.

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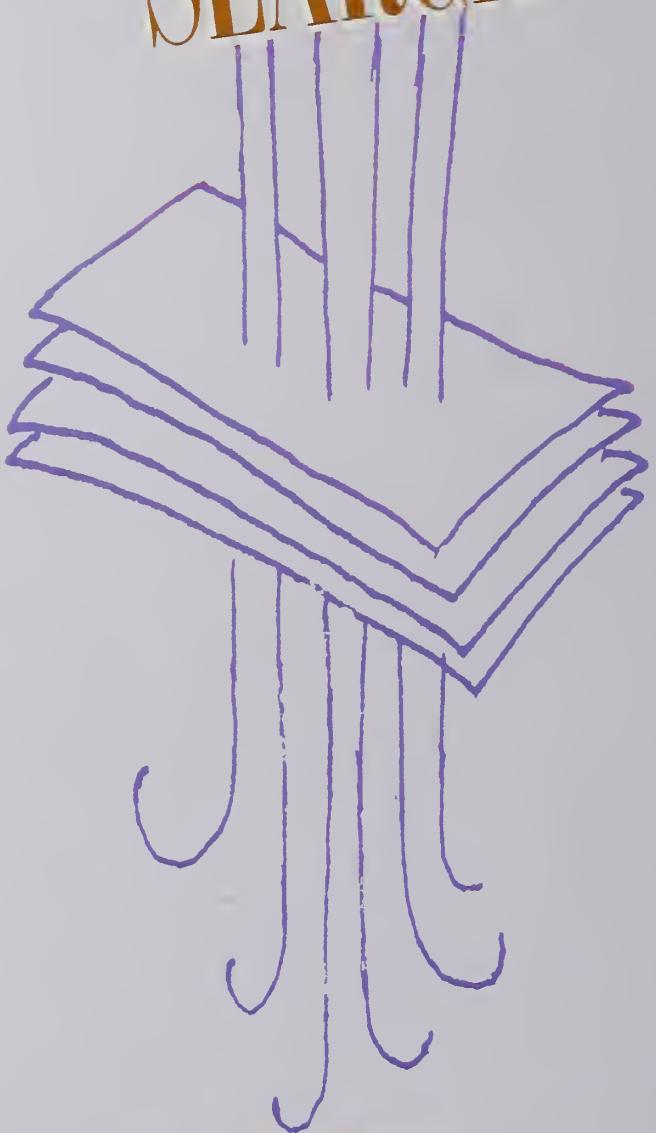
TRIALS SEARCH



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